Changes in Food Habits, Perceptions and Motivation for Healthy Eating

A Culturally Adapted Intervention among Pakistani Immigrant Women in Oslo

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Master Thesis

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Aknowledgements

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Executive Summary

Background: South Asians have a high risk of developing type 2 diabetes (DM2), cardiovascular disease (CVD) and other chronic diseases compared to other ethnic groups. Pakistani immigrants constitute the largest non-Western immigrant group in Norway, and have been found to have high incidence of overweight and obesity and other risk factors for the metabolic syndrome (MS). There are several reasons for this: early life conditions, genetics, dietary habits and physical activity all play important roles in the development of non-communicable diseases later in life. Pakistani women have a higher prevalence of DM2 than their men. They generally have low literacy, educational level and Norwegian language skills, and most of them are not employed. It has also been found that their knowledge of nutrition and health is generally low. Earlier studies indicate that lifestyle interventions may increase the knowledge and awareness of own health risk among Pakistani women with DM2, however, there is a lack of research regarding lifestyle interventions among people who are at high risk of DM2.

Aim: The aim of this thesis was to study data on Norwegian-Pakistani women's food consumption and perceptions of healthy eating before and after a lifestyle intervention, so that dietary choices and the factors affecting change can be better understood. Furthermore, it sought to study the relationship between the stages of change and actual food intake.

Methods: 196 Pakistani women, aged 25 to 62 years, were included in the 7 months lifestyle intervention, the InnvaDiab study. They were all living in Søndre Nordstrand in Oslo, and randomized into a control and intervention group. The majority was first generation immigrants. Mean age was 41.5 (95% CI = 39.8, 43.1) and 41.0 (95% CI = 39.3, 42.6) years in the control and intervention group respectively. Demographic data was collected at baseline, and measurements of height, weight and waist circumference were taken by trained staff before and after the intervention. Data were collected through an interview carried out by Urdu and/or Punjabi speaking interviewers with the help of a questionnaire. In this study, baseline and post test data

have been analyzed. Data include changes in perceptions and knowledge of the link between diet and health, changes in frequency of intake of drinks with and without sugar, intake of foods rich in fat and sugar, intake of white bread, intake of fruits, vegetables, legumes and potatoes, intake of fish, the amount of oil and type of fat used, and intake of cod liver oil and vitamin supplements. The stages of change construct, from the Trans Theoretical Model (TTM), was used to study the intentions to change dietary habits. The participants are classified according to 5 stages through which they progress during the process of changing behaviour. *Pre action* refers to the stages pre-contemplation, contemplation and preparation, while *action* refers to the action and maintenance stages. Also, baseline and post test data were used to study the relationship between movement in stages of change and changes in the dietary intake. Statistical analyses included chi-square and Mann-Whitney U tests to analyze differences between groups, while Wilcoxon's signed rank-sum test was performed to measure differences within groups. McNemar test was used to study differences in correlated proportions of baseline and post test data.

Findings: Findings showed that 40.1% and 39.5% in the control and intervention group respectively were obese (BMI $\geq$ 30 kg/m^2). About 65.% in the control and intervention group classified sugar as unhealthy at baseline, compared to 79.5% and 82.1% in the control and intervention group respectively, at post test, ($p = 0.019$ for change in the intervention group). In the intervention group, 28.1% at baseline and 51.3% at post test mentioned white flour as unhealthy ($p = 0.009$), while the percentage remained almost unchanged in the control group. Regarding foods classified as healthy, about 80% in the control group and 87% in the intervention group at baseline and post test mentioned vegetables. There was a decrease in responses in the intervention group regarding classification of meat as healthy ($p = 0.022$), while in the control group, the percentage remained unchanged. Regarding factors that can increase the risk of DM2, results showed an increased response rate with regard to low physical activity ($p\leq0.001$ in both groups) and overweight ($p<0.001$, $p = 0.052$ in the intervention and control group respectively). For the other factors, significance was only found in the intervention group: family with diabetes (p

= 0.009, p = 0.058 between the control and intervention group), and too much fat (p = 0.035).

Regarding stages of change, there was no significant difference between the control and intervention group at baseline. Data collected after the intervention, showed a shift in distribution in all stages of change variables in the intervention group, except for intentions to increase fruit intake. This was not observed in the control group. This resulted in significant differences between the control and intervention group for all variables except for fruits. In the intervention group, the proportions in the action stages at post test were significantly higher compared to baseline for some stages of change variables. These included intention to reduce fat, change type of fat, reduce sugar intake, and reduce intake of white flour. This was not observed in the control group.

Results from intake of selected foods and drinks at baseline and post test, showed a significant reduction in intake of soft drinks and fruit drinks with added sugar in the intervention group ($p \leq 0.002$). The differences between the control and intervention group were also significant ($p < 0.002$). Regarding whole fat milk and yoghurt, there was a significant reduction in the intervention group from baseline ($p = 0.027$). Intake of foods high in fat and sugar remained more or less unchanged from baseline to post test, however, the intake of sweet bakery goods was significantly increased in the control group ($p = 0.022$). This was not observed in the intervention group.

The total intake of fruits, fruit juice and vegetables, had increased from 327 to 375 g per day in the intervention group ($p = 0.031$). Fish intake was generally low in both groups, with minor increases at post test. The increased intake was significant for lean fish in the intervention group ($p = 0.040$) and fatty fish in the control group ($p = 0.023$). The total amount of fish added up to about 1 portion per week in both groups, with the greatest increase from baseline was found in the control group ($p = 0.090$).

Results from the data collected on intake of fat and the type of fat used, showed that most of the women use oil in food preparation (over 90%), while some use

margarine, butter and ghee (the latter only 1-3%). The reported amount of oil purchased per month had decreased in both groups ($p \leq 0.001$).

Those who had moved from the pre action stages to the action stages had a significant higher increase in intake of fruits ($p = 0.004$) and legumes ($p = 0.015$) per week, compared to the rest of the participants.

Treatment received analysis (TRA) showed a few changes in results compared to the intention-to-treat (ITT) analysis. This could produce differences in conclusions drawn in this study, depending on exclusion of those participants who did not attend any or only a few of the teaching lessons.

Conclusion: This study has shown that culturally adapted health education can change the knowledge and perceptions of healthy eating in a group of Norwegian-Pakistani women. It has further shown that health education in this group can increase these women's perceptions of own diet and their intentions to make their diet healthier. In addition, the women had made changes to their diet that are important in order to reduce the risk of DM2 and MS. Finally, the study has found that movement from the pre action stages to the action stages are in agreement to the changes they have made to their diet.

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Clarification of terms

Acculturation: the process that occurs when an ethnic, usually minority group, adopts beliefs, customs, values and practices of the host country (1-3). Diet acculturation represents the process that occurs when immigrants adapt their diet to the new country's dietary practices.

Ethnic group: a group whose members identify with each other, usually on the basis of presumed ancestry. They have certain cultural, linguistic, religious, behavioural or biological traits, distinct from other groups

Immigrants: people who are born abroad or have two foreign-born parents (4)

Intention to treat (ITT): a strategy for the analysis of randomized controlled trials, comparing participants in the groups to which they were originally randomly assigned (5)

Treatment received analysis (TRA): participants in randomized controlled trials are not compared based on the groups to which they were randomly allocated, but based on whether they received the treatment/intervention or not (6). In this study, participants who had attended ≤ 3 classes out of 6 were excluded from these analyses.

Type I error: rejecting the null hypothesis when it is true (7)

Type II error: failing to reject the null hypothesis when it is false (7)

Abbreviations

BMI	Body mass index (kg/m^2)
CAD	Coronary artery disease
CATS	Cognitive Activation Theory of Stress
CFGHE	Canada's Food Guide to Healthy Eating
CHD	Coronary heart disease
CVD	Cardiovascular disease
DM2	Type 2 diabetes
DPP	Diabetes Prevention Program
FDPS	Finnish Diabetes Prevention Study
FFQ	Food frequency questionnaire
GP	General practitioner
HDL	High density lipoprotein
IFG	Impaired fasting glucose
IGT	Impaired glucose tolerance
IRS	Insulin resistance syndrome
ITT	Intention to treat
MS	Metabolic syndrome
OGTT	Oral glucose tolerance test
SES	Socio-economic status

SN	Statistics Norway
SPSS	Statistical Product and Services Solutions
TRA	Treatment received analysis
TTM	Trans theoretical model
WHO	World Health Organization

1. Introduction

1.1 The master thesis as part of an intervention study

The InnvaDiab study is an intervention conducted in Oslo. Data collection started in April 2006 and ended in May 2008. The aim of the study is to influence risk factors related to lifestyle, such as physical activity and dietary habits in order to reduce the risk of type 2 diabetes (DM2) and metabolic syndrome (MS) in Norwegian-Pakistani women. People from Pakistan constitute the largest ethnic minority group in Norway (4). South Asians are at higher risk of developing MS and DM2 than other populations (8-11), and it has been reported that the prevalence of DM2 in South Asians in Norway is high compared to the rest of the population (12). In addition, Pakistani women in Norway generally have a higher body mass index (BMI), waist circumference and incidence of DM2 than their men (13). Furthermore, they are less integrated compared to children and men, and thus, much more difficult to reach.

In the InnvaDiab project, the intervention group was offered group sessions that focused on diet and lifestyle changes with regard to DM2 prevention. In addition, the women attended organized walking groups. Earlier studies indicate that life style interventions may increase the knowledge of nutrition and health among different ethnic groups and decrease the risk of DM2 and other chronic diseases (14-18). The dietary advice given to the intervention group was adapted to the Pakistani culture, to study its effects on the women's knowledge and dietary habits recommended for this group, based on earlier studies in Norway, Denmark and England (19-21) .

Co-supervisor and PhD student Benedikte Bjørge has been in charge of the part of the intervention related to diet and nutrition, studying effects of dietary education and counselling of the women in the study. The effects were measured by changes in diet, biochemical and anthropometrical parameters related to nutrition and changes in knowledge and attitudes to food and health and intentions for dietary change.

This master thesis is based on selected data from baseline and post test, collected in the study. It sought to study the changes in the women's perceptions and knowledge with regard to healthy and unhealthy dietary behaviour, as well as changes in dietary intakes from baseline to post test. The thesis has a focus on those foods which were in focus in the teaching sessions such as the intake of fruits, vegetables, legumes and fish, as well as intake of foods rich in fat and sugar. The thesis has also studied the changes in intentions to change dietary habits.

1.2 The increased prevalence of chronic diseases in a global perspective

In 2001, chronic diseases contributed to about 46% of the global burden of disease (22). About half of the deaths were caused by cardiovascular disease (CVD), obesity and diabetes. From estimates done in 2004, it was predicted that the proportion of chronic diseases would increase to 57% by the year 2020. These numbers give us an indication of the extent of the challenges we are about to face in the years to come. As mortality from communicable diseases and mortality among infants and mothers decrease, especially in developing countries, the prevalence of chronic diseases might become even higher than projected. This will again increase the number of deaths from CVD and other conditions associated with diabetes (23).

1.2.1 The life cycle approach to nutrition and the prevention of chronic diseases

Many communities in the developing world are experiencing a double burden of disease: under nutrition in infants, children and women, often in the same household, and over nutrition in the adults, especially in older women (22). Most countries in the world are undergoing a fast modernization process, moving them in the direction of a more industrialized society. The standard of living and access to services have improved. However, the downside to this are the harmful changes in dietary habits and physical activity, that in turn contribute to the increase in non-communicable diseases (22;24). One sees a trend towards an increased consumption of a diet higher in fat, particularly saturated fat, and protein. In addition, the intake of sugar is

increasing due to the consumption of soft drinks and sweet snacks. Furthermore, the consumption of traditional staple foods such as fruits, vegetables and legumes, together with a reduction in complex carbohydrates, is decreasing in developing countries (24). In addition, a modernization process usually leads to a more sedentary lifestyle due to motorized transport and labour saving equipment. However, there are also positive consequences of the urbanization and globalization processes, such as more variation in the diet in these societies (24).

The "fetal origin" hypothesis

Early life conditions, such as impaired fetal growth and development, and deprivation of food, have been seen to affect health outcomes later in life (20;22;25). This "fetal origin" hypothesis suggests that changes in fetal nutrition lead to adaptations in the developing fetus that will permanently change the structure, physiology and metabolism. This may predispose the child for lifestyle diseases later in life when exposed to an abundance of foods (20;25). This so-called Barker's Hypothesis is especially relevant to South Asians as they have among the highest prevalence of low birth weight (<2,500 grams) in the world, where Pakistan has a prevalence of 25% (20). Signs of retarded growth as an infant and small child can be detected as failure to gain weight and failure to gain height (22). In low birth weight Indian babies, one has observed low muscle mass and high percentage body fat, the so-called "thin-fat" babies. This body composition has been found to remain through post-natal period and linked to increased central obesity in childhood (26).

Other factors in childhood have also been linked to adult chronic diseases (22), e.g. raised blood pressure, impaired glucose tolerance (IGT) and dyslipidemia. Furthermore, higher blood pressure (body-mass adjusted) has been observed in children living in Pakistan compared to White children in the U.S. This too indicates that predisposing factors to chronic diseases are manifested early in life for Pakistani children (27). It is not known how and if early life conditions have affected the health status of the women in this study, however, it should be taken into consideration.

1.2.2 Westernization and urbanization

Moving from the countryside to the city causes lifestyle changes which might result in weight gain (10;26-30). Jafar et al observed a 2.5 times greater prevalence of obesity among urban residents than rural residents in Pakistan (9). Other studies have found similar trends in other Asian populations (10;20;25;26), and according to a review by Misra et al (26), the average BMI in Asian Indians[1] seems to increase with urbanization and migration. The prevalence of diabetes among Asian Indians living in rural areas of India has been estimated to about 2 %, while among Asian Indians living in urban India it is about 8 % (28). Asian Indians who have migrated to Western countries have about four times higher prevalence of diabetes than Asian Indians living in their home country. This indicates that the lifestyle changes occurring with urbanization and westernization may, to a great extent, explain the progressive increase in the prevalence of DM2 (25;28). While 63.8% of the labour force in rural areas of Pakistan is employed in the agricultural sector, the number is only 7.6% in urban areas. This difference in physical activity might explain the coexistence of CVD risk factors in urban areas of Pakistan (27).

When migrating to westernized societies, populations from developing countries change their diets to a lesser or greater extent (28). The main changes are the reduction in fibre intake and the increased consumption of animal fats and processed carbohydrates. Refined carbohydrates and animal fats have been found to increase predisposition of DM2 (31;32), so has a reduced intake of fibre in the diet (33;34). A lower glycaemic and insulin response may explain the protective effect of a high intake of whole-grain products.

[1] Asian Indians refers to persons originating from the Indian Subcontinent or South Asia, which includes Afghanistan, Bangladesh, Bhutan, India, the Maldives, Nepal, Pakistan, and Sri Lanka

1.3 Obesity and the metabolic syndrome

The metabolic syndrome (MS) also referred to as insulin resistance syndrome (IRS) or Syndrome X, is increasing worldwide. Studies have shown that Asian populations have an increased risk for this condition (8-11;27;35). There are several definitions and criteria to the term. In short, the different definitions characterize MS by intra-abdominal obesity, reduced insulin sensitivity, elevated triglycerides, low HDL-cholesterol, systolic hypertension and hyperglycaemia (11;26;36-38). Genetics, obesity, physical activity, and advancing age are all contributing to insulin resistance (36). Adiposity is the most important risk factor for this condition (39); as adiposity increases, so does insulin resistance. The risk factors that categorize MS contribute independently to CVD (36). After adjustment for total body fat and truncal skinfold thickness, it has been shown that Asian Indians still have higher prevalence of insulin resistance compared to Caucasians. Thus, it has been hypothesized that neither obesity nor distribution of fat can fully explain the high incidence of insulin resistance and DM2 in this group. It has been suggested that this is due to a primary metabolic defect (8).

Mechanisms of the metabolic syndrome

The mechanisms for MS are not fully understood. However, it has been suggested that positive energy balance (too high food intake and too little physical activity) results in abdominal obesity. This leads to the release of free fatty acids from intra-abdominal fat, which results in insulin resistance and increased glucose production from the liver. Unless the person's insulin production increases, this condition can lead to DM2 (38). In other words, MS is not a result of DM2, but DM2 is rather a consequence of MS (36;38). Many patients with MS have impaired fasting glucose (IFG) and IGT even though they do not have DM2[1]. However, they are both strong markers for the development of this disease, which may only develop years later (36;40). IFG is to a lesser extent associated with DM2 and CVD than IGT. While IFG

[1] The prevalence of IGT rises with age, while IFG prevalence plateaus in middle age. The prevalence of IGT is higher than the prevalence of IFG in Asian men and women as well as in European women and in European men aged ≥ 70 years (40).

is characterized by a raised fasting glucose, IGT is identified with an oral glucose tolerance test (OGTT), resulting in a raised 2 hour glucose level in the blood. Lifestyle interventions have been found to be effective in preventing or delaying the onset of DM2 in people with IGT (40).

1.3.1 Ethnicity and the metabolic syndrome

Very few studies have been conducted on MS in South Asians, and neither on the prevalence in Pakistan. Studies have found that South Asians generally have a high percentage of body fat, low muscle mass, abdominal obesity, insulin resistance and hyperinsulinaemia (26;39). Abdominal obesity is observed even in non-obese people from this group (8;26;39). Furthermore, they have higher percentage of body fat at a similar or lower BMI compared to non-Asians. It is possible that the tendency of thick subcutaneous adipose tissue compared to other ethnic groups might be one cause for the high prevalence of insulin resistance in South Asians. However, an older study from McKeigue and colleagues, found that insulin resistance in Asian Indians compared to Caucasians, was high even in the absence of obesity. This study found that Asian Indians have high levels of insulin even when BMI is similar to that of Caucasians (41). It should also be mentioned that the criteria for defining MS are based on data from white populations and might not be appropriate to identify the condition in Asian populations (26;35).

1.3.2 Suggested cut-off points for BMI and waist circumference among South Asians

Being overweight (BMI $\geq$ 25 kg/m^2), increases the risk for insulin resistance and DM2. However, this BMI cut-off point is mainly based on data from populations of European descent (35;39;42). Thus, the need for new cut-off points for Asians has been proposed in order to recognize those at risk. Studies suggest that the same BMI for certain ethnic groups may reflect a higher risk for developing DM2 (9;43;44). Thus, using the standard BMI may lead to inadequate screening in high-risk ethnic groups.

The WHO Expert Consultation has recommended that the current WHO BMI cut-off points should be used by all countries. However, they conclude that current data do not necessarily indicate a clear BMI cut-off point for all Asian populations. Thus, for many of these populations additional cut-off points have been identified as 23.0 kg/m^2 or higher, representing increased risk, and 27.5 kg/m^2 or higher representing high risk within the classifications "normal range" and "pre-obese" respectively, and should be added as points for public health action (9;35;45). The International Association for the Study of Obesity and The International Obesity Task Force have also suggested new cut-off points for BMI for the definition of overweight (23.0 – 24.9 kg/m^2) and obesity (≥25.0 kg/m^2) in Asian populations (2) which is similar to the WHO's recommendations.

Similar to BMI, it has been suggested that waist circumference should be adjusted for South Asians. The internationally accepted cut-off points for waist circumference are 102 cm for men and 88 cm for women (39;41;45;46) while waist circumferences of ≤90 cm for men and ≤80 cm for women is considered to be more appropriate for South Asians (26;35;39;41;46).

1.4 Type 2 diabetes

The most common type of diabetes mellitus is DM2, which generally appears late in life (36), usually after the age of 40 (47). However, as body weight increases among populations world wide, the prevalence among younger people is increasing.

1.4.1 Diabetes and cardiovascular disease

Diabetes is an independent risk factor for CVD in both men and women. People with CVD and diabetes have a worse prognosis for survival than CVD patients without diabetes. This explains why about 65% of diabetic deaths are caused by CVD (36) . The reasons why diabetic patients have a high prevalence of CVD are multiple, including severe coronary atherosclerosis, prolonged hypertension and hyperglycaemia, microvascular disease, and autonomic neuropathy. However, cigarette smoking, hypertension, and high serum cholesterol are all independent

contributors to CVD in diabetics (36). Also, predisposing factors, such as obesity, sedentary lifestyle, heredity, sex and high age may increase the risk of CVD and diabetes. Both diabetes and CVD can be prevented by controlling these predisposing risk factors. Modification of life style, the prevention and treatment of obesity, and encouraging physical activity should be part of the public health strategy (36;48).

1.4.2 Type 2 diabetes, obesity and ethnicity

In Norway, it is estimated that about 225,000 people have DM2. About half of these are not aware of it (47;49). Every year approximately 6-7,000 people are diagnosed with DM2 in Norway (47). In the Global Prevalence of Diabetes report from 2004, the prevalence of diabetes in 2000 and projected numbers for 2030 were estimated (23). For adults worldwide aged 20 and older, the prevalence of diabetes (type 1 and type 2) was calculated to be 2.8% in 2000 and 4.4% in 2030. This adds up to 171 million people in 2000 and 366 million in 2030. This great increase is based on estimates in population growth, aging, urbanization, increased prevalence of obesity and reduced physical activity. Even if the number of obese people stays stable, it is anticipated that the prevalence of diabetes will double due to an ageing population worldwide and the process of urbanization.

In developing countries, the majority of people with diabetes are in the age group 45 to 64 years of age. In developed countries, however, the highest occurrence of diabetes is found in people aged 64 and older. The projections for 2030 indicate that the greatest increases of diabetes will be in India, China and the U.S. (23;50). However, Pakistan is number six on the list for the estimations for 2000 and five for 2030, 5.2 million and 13.9 million respectively.

1.4.3 Type 2 diabetes in immigrant groups

There is growing evidence that certain ethnic groups are predisposed to develop DM2 when exposed to certain environmental conditions (8;27). South Asians have a higher prevalence of diabetes than Caucasians even when they live in similar environmental conditions. In the U.S., immigrant groups from India, Pakistan and Bangladesh have

the highest predisposition for DM2 (8). It has been estimated that the prevalence of DM2 among Asian Indians in the West is about 19%, while it is only about 5% in Caucasians. Similar results have been found in other studies (42).

Obesity and sedentary lifestyle are strong determinants for DM2 and other lifestyle related diseases (8;10;16;27;30;39;41;48). As family history of DM2 is an established risk factor for the disease, the common practice of inter-family and cousin marriages among South Asians might increase the risk (10).

In certain areas of Oslo, the prevalence of diabetes is 21 % in men and 36 % in women aged 40 – 59 of South Asian origin (12). Similar, but somewhat lower estimates in Oslo, have been reported by others (30). For comparison, in the Oslo Health Study 3% of men and 2% of women aged 40-49 were reported to have diabetes, while the actual prevalence of total diabetes was estimated to be about twice the self-reported (49). Moreover, gestational diabetes has been found in 80 % of Pakistani and Indian women in Oslo, compared to 20% among ethnic Norwegian women. Figures from Pakistan and Norway cannot be directly compared due to several reasons, but the figures suggest that the prevalence of DM2 increases after migration to Norway (20).

1.4.4 The link between early life conditions, lifestyle factors and type 2 diabetes

Early life conditions, such as maternal deprivation, increases the risk of having low birth babies (<2500 g). Children born with low birth weight have higher risk of high blood pressure, DM2, CHD and other chronic diseases later in life (22). Westernization, urbanization and globalisation change the dietary composition in many developing countries. This usually leads to an increased daily energy intake through consumption of saturated fats and refined carbohydrates and a more sedentary lifestyle (22;24). These factors have a great impact on the predisposition of obesity and DM2. For each kg of increased body weight it has been estimated that the risk for DM2 increases by about 4.5 % (51). The abnormal body composition in South Asians; a high percentage body fat, abdominal obesity, excess truncal

subcutaneous fat and low muscle mass, can be explained by maternal and early childhood deprivation, and an imbalanced diet (39). These interactions of genetics, perinatal, nutritional and other factors can lead to insulin resistance, DM2 and CHD (Figure 1).

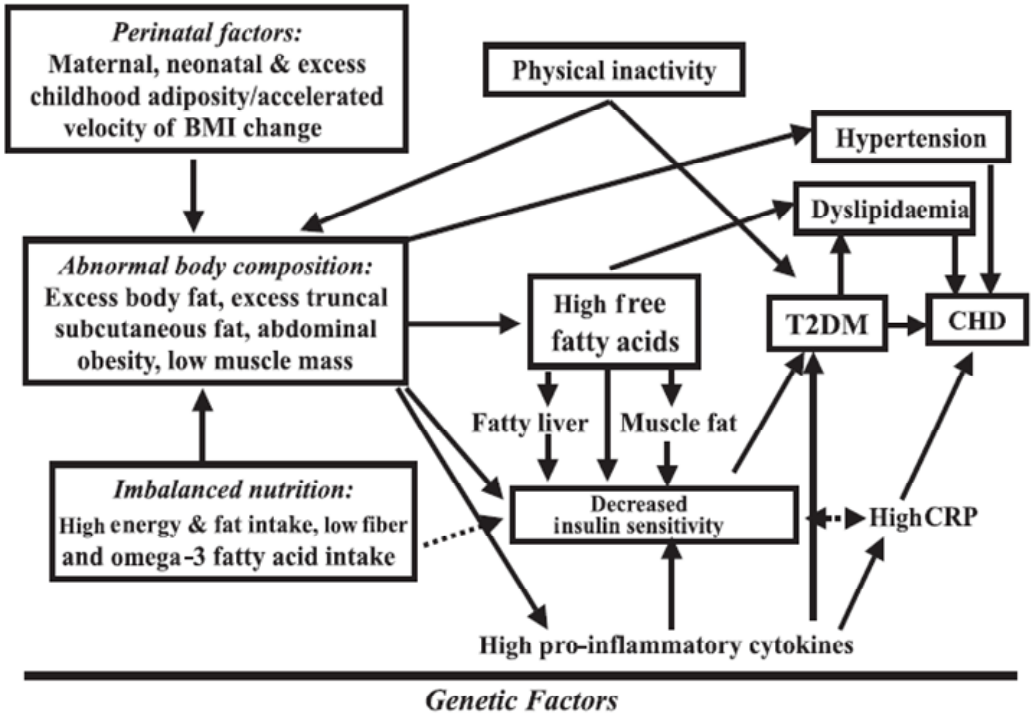

Figure 1: Interactions of genetic, perinatal, nutritional and other factors involved in the development of insulin resistance, DM2 and coronary heart disease in South Asians. (Dotted lines represent weak relationships.) (39)

1.4.5 The importance of early intervention

DM2 is the result of years of metabolic stress and insulin resistance. Long before hyperglycaemia appears, the acceleration of atherogenesis starts. Thus, detecting the risk factors associated with MS in patients at risk for DM2 is crucial. In other words, regularly measurement of weight, abdominal obesity, blood pressure, triglycerides, and cholesterol is needed to delay onset of DM2 and reduce the risk of CVD (18;36).

The impact of diabetes is high when it comes to morbidity, vision loss, amputations, renal failure, CVD, and mortality from heart disease and stroke (36;48). Furthermore, it has a great impact on the economic healthcare system. As people with diabetes

have an extended pre-diabetic phase that can be easily identified, early lifestyle intervention is crucial to prevent diabetes and hence its complications (48). Moreover, lifestyle modifications have also shown to improve metabolic abnormalities such as dyslipidemia, hypertension, obesity, and pro-coagulant and pro-inflammatory activity that are associated with the development of diabetes and its complications (48).

The Finnish Diabetes Prevention Study (FDPS), the Da Quing study, and the Diabetes Prevention Program (DPP) found that lifestyle changes, focusing on diet and physical activity, had a great impact on the progression of DM2 (16;48). The FDPS showed that people who lost ≥ 5% body weight had a significant lower likelihood of developing DM2 than those losing less weight or none at all. To date, we know little about diet intervention and weight loss among South Asians in the Western part of the world. Furthermore, there is a lack of knowledge concerning which factors that influence lifestyle changes among immigrant groups.

Misra et al have proposed the following guidelines to prevent and control MS in Asian Indians (26):

1. Lifestyle changes should be encouraged from childhood. Encourage calorie restriction to prevent obesity, abdominal adiposity, and insulin sensitivity. Also, focus on physical activity.
2. Maintenance of optimal weight, with a BMI between 18.5 and 23.0 kg/m^2 and a waist circumference of less than 90 cm for men and 80 cm for women.
3. Creating awareness by public information campaigns
4. When detecting one risk factor for insulin resistance, a further examination should follow to detect other risk factors
5. Increased focus on providing adequate nutrition during the intrauterine period, and to prevent early-life adverse events
6. Culturally appropriate programs should be implemented to prevent IRS

1.5 The Pakistani population in Norway

During 2006, immigrants to Norway increased by 28,600, which is the greatest increase ever seen here (4). At the beginning of 2007, there were about 415,300 people with an immigrant background living in Norway, which adds up to 8.9 % of the total Norwegian population. Moreover, 31.4 % of the inhabitants in Oslo were of immigrant background by 01.01.07. At this point there were 28,278 immigrants with a Pakistani background in Norway, which makes them the largest immigrant group from outside of Europe. The majority of these, 85%, live in Oslo and Akershus. The majority of this group comes from the rural area of Punjab and many have low level of education and occupations of low income (20;25;52).

The first Pakistanis to arrive came to work here in the 1970s. While some have returned to Pakistan, many have stayed, and today most Pakistani immigrants come to join family members in Norway (53). At the beginning of 2006, about 3 in 10 first generation immigrants had lived in Norway for more than 25 years.

1.5.1 Facts of Pakistan

Pakistan is an Islamic country, with about 96% of the population of 165 million, being Muslims (54). The people represent many different groups and speak a great variety of languages. Urdu is the national language, while English is mainly the language used in official matters and by the higher educated part of the population. The regional languages are Punjabi (44.2%), Pashtuns (15.4%), Sindhi (14.1%), Seraiki (10.5%), Urdu (7.6%), Balochi (3.6%) and others (4.7%). Many people in Pakistan are bi-lingual; however, they generally manage their regional language better than Urdu. The educated part of the population speak at least three languages; the regional language, Urdu and English (54).

1.6 Immigration and changes in food habits

1.6.1 Acculturation

Several changes occur with immigration, such as access to health care, changes in physical activity, and diet. Acculturation is commonly used to explain the process that occurs when an ethnic group, usually a minority group, adopts beliefs, customs, values, and practices of the host country (1-3). Diet acculturation represents the process that occurs when immigrants adopt their diet to the new country's dietary practices.

Studies that have investigated the association between acculturation and the risk of diabetes, have shown inconsistent results when it comes to the effect on dietary changes (1) . This is mainly because the health effect of acculturation varies by country of origin, the level of education, physical characteristics (e.g. skin colour), whether the immigrants come from urban or rural areas, and several other factors (1-3;55). However, South Asians seem to be more vulnerable to the Western lifestyle and the subsequent acculturation, e.g. by developing DM2 and glucose intolerance at a lower BMI than other ethnic minority groups.

Dietary acculturation is a complex process. Several theories have been proposed, however, they generally describe acculturation as a staged, multidimensional, dynamic and complex process (3). Immigrants adopt their diet by finding new ways to use traditional foods, exclude some foods, and/or consume new foods. Also, if traditional foods and ingredients are unavailable or too expensive, it might result in an increased consumption of foods of the host country. In result, immigrants may maintain their traditional dietary patterns, completely change to the host country's foods and eating habits, or keep some of their traditional habits and incorporate certain of the host country's dietary practices, described as biculturalism.

1.6.2 Traditional Pakistani food

Traditional rural diets in the Indian subcontinent are high in grains, vegetables and fruits, and low in meat and dairy products. These dietary habits are in accordance to

the recommendations of the Norwegian Directorate of Health (56) as means to reduce the risk of development of chronic diseases. Thus, the traditional Asian diet is more in accordance with these recommendations than the Norwegian diet.

The traditional diet in Pakistan consists of three hot meals per day (25;57). Chapatti or rice are the staple foods of lunch and dinner, served together with one or more stews (salen). Salen is a curry which may include vegetables, beans or lentils, and sometimes meat, poultry and fish, together with numerous spices and some oil, ghee or other types of fat (25;57). The term roti or "our foods" is used to describe a complete meal consisting of curries, chapattis, and/or rice together with side dishes such as achar (pickle) and raita (yoghurt with cucumber and mint) (58). Pulses, fruits and vegetables are also part of the traditional diet. The use of butter and margarine is often restricted for many households in Pakistan as these items are too expensive.

Changes in the Pakistani diet

Diet changes among Pakistani immigrants in Western countries are first of all related to an increased consumption of meat, oil, fruits, sugar, dairy products, fish and boiled potatoes (3;20;25). On the other hand, most Pakistanis report to have a decreased consumption of certain types of fat, such as butter and margarine. Due to affordability, there has also been an increased incorporation of "luxury items" such as ghee (a type of clarified butter that originated in the Indian subcontinent (59)), meat and traditional sweets into the everyday menu (58). Thus, dietary acculturation can result in healthy and unhealthy dietary changes. Research, mainly from the US, Canada and Great Britain, also indicate that changes towards the "Western" diet may result in an increase in foods rich in sugar and fat, like more "convenience foods", meat products, soft drinks or alcohol (2;26;29;55;60), and a decreased intake of traditional foods, such as beans, lentils, fruits and vegetables (3;20;25;26). Varghese et al found that only 25% of the respondents in their study (Indian immigrants aged 10 and above) met the minimum recommended intake for grains, vegetables and fruits as according to the Canadian Food Guide for Healthy Eating (CFGHE) (55). Thus, when using Western foods, it seems that minority groups adopt the less healthy

aspects of the Western diet, mainly because they want to serve something different, or shortness of time (3;60).

1.6.3 Food habits among the Pakistani population in Norway

Studies have shown that Pakistanis, after immigration to Norway, change their diet towards a Norwegian meal pattern of 1 hot meal a day (20;25), while only 7 % continues with the meal pattern which consists of three hot meals a day. Most Pakistani immigrants report a bi-cultural food pattern, but with the greatest emphasis on the traditional dishes for dinner. This is consistent with findings from other studies, where immigrants showed a higher tendency to consume traditional foods at dinner, while breakfast, lunch and snacking were more "Westernized" (3;58).

The concept of sharing

In contrast to breakfast and lunch, dinner is considered a "proper meal", probably because dinner has become the only meal where the whole family is gathered. However, a study of Pakistani immigrants in Britain found that the importance of dinner is also related to the immigration of wives and children of the Pakistani men (58). Following the family reunions, religious practices and family and community values have become more central in the immigrants' everyday life. The importance of the whole family being gathered, consuming a shared meal, prepared and served in a handi, a large pot from which everyone can help themselves, have become a part of their identity as immigrants to a new county. This act of commensality, the sharing of food consumption, is often also extended to the community. Commensality has by some been described as obligatory. Eating differently or refusing foods can lead to loss of identity or cause offence.

There also exists a system of gift-exchange, *lena-lena*, in the Pakistani community, which include the giving and sharing of South Asian sweets and dinner/meal invitations. This has been found to be a vital part of Pakistani life in a new country (58). This system expresses honour, status and prestige; it is highly visible and often occurs in big events such as weddings. However, another aspect is the creation of a

social network, including neighbours and other parts of the community, helping them to keep important aspects of their traditions.

1.6.4 Cooking practices

Lawrence et al (60) did a focus group study of young women from minority ethnic groups. The discussions in the group of Pakistani/Bangladeshi women revealed that these women's cooking had been learnt from the older generation of women in their family. These women put a lot of effort into their traditional cooking (20;60) but according to themselves, they know very little about Norwegian dishes. Thus, changing the meal pattern into a more Norwegian one might reduce the cultural importance of certain meals and thus, lead to less concern about the composition of these meals. Combining this with less physical activity, may lead to weight gain (20).

Furthermore, although it is the women who carry out most of the shopping and meal preparation, what is actually consumed is affected by several factors. These include the access to food and the food preferences and tastes of all family members, health aspects, work schedules, social relations, food beliefs, stress, climate, and season (20;60).

1.7 Perceptions of healthy eating

Classification of foods is important when it comes to making food choices. Health has been identified as being a central part of this classification of foods in Western societies (61). Moreover, today the science of nutrition is becoming more and more important in people's daily lives. Now, new elements of foods must be taken into consideration in order to determine their healthiness, such as the type of fat and how to combine foods in order to consume a nutritionally balanced diet.

In many societies there exist religious beliefs and ideas about how certain types of foods may prevent or cure different types of diseases (62). Foods are often classified differently in Western societies compared to other parts of the world. For instance being hot/cold or yin/yang. Thus, the meaning of "healthy foods" concerns both the

nutrients these foods provide to the body in order to maintain its functions, and the symbols and meanings related to the food in different cultures.

1.7.1 Classification of "healthy" and "unhealthy" eating

When looking at health-related dietary change, one has to consider the interpretation given to "healthy" and "unhealthy" eating. There are a great number of interpretations, resulting in the broad nature of the concept "healthy eating" (61). This is likely due to the wide range of nutritional advice and sometimes conflicting information/views on the subject. People gather information on food and nutrition from a number of sources, such as television, food labels, food manufacturers and health professionals (62). The knowledge communicated by health professionals often concerns the relationship between diet and chronic diseases, such as cancer, diabetes and coronary heart disease. From this, people must give meaning to the information and decide whether it is useful and can be applied in their daily life. For example, Pakistani women appear to have quite a good understanding of what kinds of foods and cooking methods that are healthy and unhealthy (e.g. oil versus butter/ghee) (60). However, the dietary practices do not necessarily reflect this.

To effectively promote healthy eating, there needs to be a better understanding of the factors that affect eating behaviour (63). One of these factors is people's perceptions. By measuring perceptions, including meaning, understanding, views, knowledge, attitudes and beliefs, one might be able to relate this to people's behaviour.

Perceptions of "healthy" and "unhealthy" foods/eating behaviour appear to differ between cultures and societies. However, what people agree on is that "healthy" foods and eating behaviour have a positive effect on your body and health, while eating "unhealthy" foods has a negative influence on your body, and can make you sick. There appears to be many gaps in the knowledge on perceptions of healthy eating (63). Little information is available considering the influence of perceptions on healthy eating, on food choice and eating behaviour, and how messages from information sources affect perceptions.

1.7.2 Perceptions related to Pakistani way of eating

Pakistanis describe foods as “strength foods” and “weak foods” (58). “Strength foods”, such as fried South Asian foods are thought to provide the body with energy. “Weak foods”, such as boiled, grilled, or roasted foods that the *goray*, the White, would prefer, are “light-weight foods” that are easy to eat. These kinds of foods are thought to have weakening effects and/or lead to lack of satiation. They are also thought to undermine people’s ability to fulfil their obligations to others and have been described to be bland, tasteless and therefore unpalatable by people in the Pakistani community (57;58). Furthermore, people from this community have reported that their traditional meals are supposed to be prepared by frying, rather than boiling.

South Asian foods have also been described by Asian Indians as being “dangerous” and “damaging” mainly due to a high fat or sugar content (58). E.g. roti was thought to be dangerous, because it was said to “turn into sugar”. However, more important than many traditional foods being dangerous was the aspect of identity in regard to their diet. This aspect of their diet was something they were unwilling or not able to change.

The process of changing one’s diet is complex. Lawton et al (58) found that Pakistanis who try to change their way of eating in order to improve their health, try to find different strategies, such as replacing an “unhealthy” ingredient with a “healthy” one, or reducing their portion sizes. This is sometimes practiced in secrecy in the kitchen where the meal is being prepared, in order to maintaining their identity and taking care of their health condition without being different from the rest of the family/community.

1.8 The challenge of giving dietary advice to South Asian ethnic groups

As already mentioned, prevention is crucial in dietary counselling. However, this has been described as difficult in Asian populations partly because their traditional way

of thinking is that health is the responsibility of health professionals and the emphasis on faith (if God will) (20). In a study of a population of diabetic Pakistani Moslems in Britain, only 15% of the patients came to the doctor to learn more about diabetes or how to control it for themselves (64). Most wanted reassurance that their blood sugar levels were fine. This external locus of control implies that many patients in this group do not feel that they have the power to alter their own health status.

As different cultural beliefs and attitudes are often barriers to patient compliance, and since many health workers do not have knowledge in this area, they underestimate the impact of these beliefs on lifestyle. For instance, research show that hot and cold foods are central in food preparation and contribute to the food choices Pakistani women make (20).

Norwegian health personnel often encounter challenges when offering nutrition information to immigrants (20;65). This is first and foremost evident when taking dietary anamnesis, patient adherence, and meeting the expectations of the patient. Often, this is due to the language, differences in behaviour, perceptions and expectations concerning health and treatment of the disease. For example, the terms “diet” and “diet control” have been reported as being confusing. Respondents in one study thought this meant that they needed to cut down, rather than change how and what they ate (58). Pakistani-born persons living in Norway have reported a wish for more advice based on their traditional food habits (65). Furthermore, many immigrants want more concrete instructions rather than general information and advice on how they can take care of their disease themselves.

Together with environmental factors, education is crucial to change behaviour. People are more likely to change their eating behaviour when they learn about the relationship between food and health. Furthermore, education programs adapted to the culture of the participant have shown positive effects in terms of lifestyle changes (65).

1.8.1 Reaching hard-to-reach populations

Clear verbal communication is important when meeting with patients in the health care setting. Verbal communication has three functions: 1) developing a relationship with the patient, 2) gathering information about the patient, and 3) sharing information with him/her. Low literacy/illiteracy is one of the most significant barriers to health, as it makes it hard to access health care and health information, as well as following treatment plans and advice from health care workers (66). In the Pakistani community illiteracy tends to be more frequent when the person is female, older, and Punjabi speaking (64). In Pakistan, only 43% of the population 10 years and older is literate, 54.8% and 32% among men and women respectively, according to the Ministry of Economic Affairs and Statistics (54). The actual numbers are probably even lower.

The focus on Pakistani women

The focus on Pakistani women in the InnvaDiab project is partly because they are in charge of preparing the meals and influence the food patterns in their family. However, more importantly, Pakistani women have been found to have difficulty understanding diabetes information that is understandable to other patients, and how to use this information in order to manage their health condition. This results in poorer glycaemic control (14). Thus, situations where applied knowledge is needed, are less dealt with by illiterate patients, mainly women (14;26). Furthermore, Pakistani women often do not go out alone, and might thus be restricted from access to health care (14;26;67). As they generally have lower literacy levels than men, they are less likely to interpret written information (14;26). In Britain, it is common to find women from first generation immigrants from this community that have never been to school and cannot read in any language (64).

In order to understand what the health worker is trying to communicate, the patient's level of Norwegian is crucial. Most immigrants with a Pakistani background living in Norway have a low level of education. Compared to other minority groups in Norway, they have received the least hours of courses in Norwegian language, and

women consider their Norwegian language skills to be poorer than men's. Among Pakistani immigrants, 28% of the women and only 4% of the men consider their ability to speak Norwegian to be poor or very poor. 33% of Pakistani women consider their Norwegian skills to be poor or very poor when it comes to talking to their doctor about their health condition. Their poor knowledge of the Norwegian spoken language is probably due to their low levels of employment outside the household. Only 4 out of 10 Pakistani women are employed, compared to 7 out of 10 men. Being an employee is important in order to improve Norwegian language skills. In addition, compared to other minority groups, the difference in language skills between men and women is greater among Pakistani immigrants (52).

Pakistani women at increased risk

Pakistani women are also at a higher risk of developing excess weight than men (9;11;13;27;30;42). In the largest city in Pakistan, Karachi, one in four adults aged 40 years or older have been found to suffer from coronary artery disease (CAD), and women have about 1.5 the risk of men to develop this condition. Women have also been found to have a higher prevalence of obesity, central obesity, hypertension, and left ventricular hypertrophy than men (9;11;26;27;30;42;67). Obesity has been estimated to be about double in Pakistani women compared to Pakistani men living in Oslo (13). Risk factors for chronic diseases have been found to be greater in women at all ages, and the differences appear to increase in magnitude with age (27). Furthermore, South Asian women are much more sedentary compared to the men and compared to women from other ethnic groups, which increases their risk of developing DM2, CVD etc (26).

1.8.2 Culturally adapted health education

Many patients do not speak or read Norwegian well, and cultural and religious holidays might make it difficult for patients to meet for appointments in clinics at certain days. Furthermore, some patients are not supposed to speak openly to individuals of the opposite sex, and women might not be allowed to travel to appointments by themselves (14). These are cultural factors that might not be

recognized by health workers of ethnic Norwegian origin, and thus, can be the cause of misunderstanding between the health worker and the patient.

Problems with communicating with ethnic minority groups are related to the distinctive language and cultural differences compared to the general population (14). Little focus has been put on health issues in these groups, and many projects to improve knowledge and awareness of diabetes, are often short-term projects with problems in communication.

In a study of Pakistanis with DM2 in Britain, researchers studied knowledge of diabetes in women and illiterate patients (64). They found that these patients had less knowledge and poorer glycaemic control and that they found it more difficult to learn how to put their knowledge into practice in daily life. When given health education that was culturally adapted, their knowledge of diabetes improved significantly compared to a control group (68), even though their glycaemic control did not improve. It was suggested that this group may need a more intensive, culturally adapted health education (64).

1.9 Lifestyle transition: the process of change

Changing one's lifestyle is often a complex process. Furthermore, migrating to a country with another culture, tradition, different health beliefs, and a different lifestyle, usually challenges the transition of change even more. Changes imply phenomena occurring over time and involve progress through a series of changes (69;70). Historically, behavioural change was often said to be a finite event, equivalent to taking action. People had changed when they had quit abusing substances such as alcohol, drugs or tobacco. Now we know that change is a process, including several stages. Behaviour change is not a linear movement through these stages, but rather progressive, regressive, spiralling or static (71). Some people stay in one stage for long periods of time, and some skip one or more stages.

1.9.1 The stages of change

The Transtheoretical Model (TTM) uses stages of change to integrate processes and principles of change from across major theories of intervention (69). Originally, it was developed for smoking cessation, however, it is now used for several health behaviours, including diet and physical activity (71). The model consists of three dimensions: the central organizing construct (the stages of change), the dependent variable dimension (behaviour, decisional balance, and self-efficacy or temptation) and the independent variable dimension (the processes of change) (72). Of these, the most widely used is stages of change, which helps to identify the types of interventions that will be most effective at each stage of change. However, it is also used to measure motivational change in intervention studies. Stage of change is the temporal dimension of motivational readiness to change health behaviour. It involves progress through a series of five stages (69-73). Studies suggest that adopting a healthful diet is a staged process. Thus, moving from one stage to the next can be used as an indicator of the effectiveness of the intervention (74;75).

Pre-contemplation is the stage in which people have no intention to take action in the foreseeable future, usually measured as the next six months. There might be several reasons why people may be in this stage, e.g. that they are uninformed or under informed about the consequences of how they are behaving, or that they have tried to change several times, without success and have given up. People in this group tend to avoid reading, talking or thinking about their behaviours. Among health professionals, these people might be categorized as unmotivated clients or as not ready for therapy, so-called “hard to reach” (69-73). People in *Pre-contemplation* tend to underestimate the benefits of changing their behaviour and overestimate the costs. However, they are not aware of this, and thus, it is difficult for them to change (70).

People in the *Contemplation* stage intend to change within the next six months (69;70). They understand their situation and the need for change. Furthermore, they are more aware of the benefits of changing, but they also see the costs of this. The

balance between the costs and benefits can make people in this stage ambivalent, resulting in some of them getting stuck in this stage for long periods of time.

Preparation is the stage in which people intend to take action in the immediate future, usually within the next six months (69;70). They have usually taken some significant action the past year. These people usually have a plan of action, e.g. talking to their dietician or doctor, joining a health education group and so forth.

In the *Action* stage people adopt new behaviours (69;70;72;73). They have made obvious changes in their lifestyle the last six months that is sufficient to decrease the risk for disease (69;70).

Maintenance is the stage in which people maintain the changes they have made (69;70;72;73). According to theory, people in this stage work to prevent relapse (69;70). However, they are less tempted to relapse and more assured that they will continue with these changes. The reasons why people are at a greater risk of relapsing in the *Action* stage are many. However, one of the reasons is that they are not prepared for how long they have to make a great effort to change and progress into *Maintenance* (70).

Some also include the stage of *Termination* as part of the Stages of Change construct. This is the stage where people are no longer tempted (69;70). No matter what situation they are in or how they are feeling, they will not be triggered to return to their old habits. While the final goal obviously would be to enter this stage, for most people the best they can achieve is the *Maintenance*.

Decisional balance says something about how the individual weigh the pros and cons of changing. Self-efficacy is people's situation-specific confidence of managing situations where it could be a high risk of relapsing. In other words, resisting temptation (69). The processes of change reflect how people change, in other words what activities they use to progress through the stages (69;70).

1.10 Aims and research questions

The main aim of this master thesis is to analyze data on Norwegian-Pakistani women's food consumption, perceptions and intentions for healthy eating before and after intervention, so that dietary choices and the factors affecting change can be better understood. Furthermore, the thesis seeks to understand the relationship between the stages of change and actual food intake.

In the InnvaDiab project, one of the aims is to investigate how dietary intake is linked with perceptions and knowledge of healthy eating in Pakistani women, and compare the effect of the intervention with the control group. Some of the factors that are thought to influence dietary intake are knowledge, attitudes, social influence, and physical/economical environment (61;76) . The questions in the questionnaires are based on these factors. Thus, in order to change the diet consciously, knowledge and perceptions of diet and health are believed to be crucial, and this will be studied in the thesis. Earlier studies, both quantitative and qualitative, have been carried out to determine intake of foods and nutrients, and changes in eating habits in South Asian populations after immigration to Western countries (20;25;58;60). However, it has also been found that immigration has both positive and negative effects on lifestyle, such as physical activity and dietary habits. Knowledge of the link between chronic diseases and lifestyle has been reported to be relatively low in this group. The women in the intervention group of the InnvaDiab study have received health education that was adapted to their culture. This approach has earlier been found to increase knowledge of diabetes in Pakistani women with DM2 (14;64). To date, we know little about diet intervention and weight loss among South Asians in the Western part of the world. Furthermore, there is a lack of knowledge concerning which factors that influence lifestyle changes among immigrant groups.

The following research questions were addressed:

Has the intervention had an impact on:

1) Perceptions and knowledge of the link between diet and health?

- Has there been a change in the women's perceptions of healthy and unhealthy dietary behaviour?
- Is there a difference between women in the intervention group and the control group regarding their perceptions?
- Has the women's knowledge of what lifestyle factors and types of foods that can increase or decrease the risk of DM2 changed?
- Is there a difference between the women in the two groups regarding knowledge of these factors?

2) Intentions to change dietary habits?

- Are the participants more motivated to change dietary behaviour after the intervention?

3) Frequency of intake of selected foods?

- Have the participants changed their intake and is there a difference between the intervention and control group regarding:
    - Intake of drinks with and without added sugar?
    - Intake of foods rich in fat and sugar?
    - Intake of fruits and vegetables, legumes and potatoes?
    - Intake of fish?
    - The amount oil and type of fat used, and the intake of white bread?
    - Intake of cod liver oil and vitamin supplements?

4) Is there a relationship between movement in stages of change and changes in dietary intake of selected foods?

2. Methods

2.1 Study design

The InnvaDiab study included 200 Norwegian-Pakistani women. The sample was randomized into a control group and an intervention group, with 100 participants in each group. 196 participants were eligible for the study; 99 in the intervention group and 97 in the control group. The intervention ran for 7 months, during which the women in the intervention group received a culturally adapted lifestyle education program, and the control group received general advice, following the existing treatment offered in primary health care. Data were collected with the help of a questionnaire, including FFQ, questions on perceptions and knowledge of healthy eating, as well as questions on intentions to change (the stages of change construct).

Prior to the intervention, a pilot study, consisting of seven women, was carried out. These women were not part of the 200 included in the study. Based on these results, revision was made in order to improve questionnaires.

In the present master thesis, a selection of data collected at baseline and post test in both the intervention and control group, was analyzed. The data was derived from the culturally adapted questionnaire, including food frequency questions (FFQ).

2.2 The recruitment process and study population

The recruitment process started April 2006 and was completed July 2007. In order to recruit intervention subjects, a multi-recruitment strategy was carried out. First, about 100 general practitioners (GPs) were informed via letters and visits by project workers. However, in all, this recruited only two women to the intervention. Thus, other means of inclusion tools were carried out. These included approaching women at the Holmlia Health Care Centre, giving presentations of the project in mosques and after Norwegian language classes, and approaching women at their gatherings at the local pool, and at big gatherings in public places. The women were given a verbal

invitation to participate in the project. As many women in this group have a low level of literacy, oral information is much more comprehensive and reaches more people. Furthermore, some women were included by using word of mouth, or by asking family members and neighbours of the team members to participate. Some women had already developed DM2 and thus, could not be included.

Inclusion criteria were:

- Women living in Norway and born in Pakistan or women born in Norway by Pakistani parents
- Diagnosis of DM2 less than 6 months
- Impaired glucose regulation:
    - 2-hour values after oral glucose tolerance test (OGTT) 140-199 mg/dl and/or
    - Fasting blood glucose 95-125 mg/dl
- Having received information about the study and given a signed consent
- 25 years or older
- Physically capable of attending the group sessions of physical exercise of one hour

Exclusion criteria were:

- Type 1 diabetes
- Positive auto antibodies (Anti GAD, anti IA2)
- Diagnosed with DM2 more than 6 months ago
- Using medication for DM2
- Pregnancy or breastfeeding at start of intervention
- Suffering from heart attack or stroke the last 3 months
- Already participating in organised physical exercise

If DM2 was detected in any of the participants, they were informed and referred to their GP right away. The GP would also receive a letter with test results and was encouraged, together with the patient, to make the necessary lifestyle changes in

order to prevent further progression of the condition. If it was necessary to initiate diabetes medication, the participant was excluded from the study.

Four women were excluded from the study due to not meeting the inclusion criteria: one subject was under the age of 20, one did not have two Pakistani parents, and the third woman was not able to complete the treadmill exercise. Furthermore, one woman reported to breastfeed after inclusion.

The Pakistani women, who participated in the intervention, were at high risk of developing DM2 and/or MS, as 25% had abnormal fasting or 2 hour glucose levels. Pakistani women were chosen as the target group as they have a higher incidence of obesity and DM2 than their men, they are less integrated compared to children and men, and thus, much more difficult to reach. Furthermore, the women are responsible for the family's food and meal preparation and face many challenges concerning diet acculturation, such as changing the traditional foods, gathering the family for common meals, and preparing Norwegian dishes. Thus, they can provide detailed information on the diet. In addition, people from Pakistan constitute the largest ethnic minority in Norway (4) .The city area of Søndre Nordstrand was chosen as the study area as this urban part of Oslo has the highest percentage of people with immigrant background (41%) (77), and also the area with the highest percentage of Pakistanis (12%) (78).

2.2.1 The intervention

Culturally adapted health education

The intervention included a combination of individual counselling and group sessions as well as organized exercise groups, and was carried out by the two PhD students Benedikte Bjørge and Victoria Telle Hjellseth. The individual counselling was a brief session where the participants were given dietary advice based on the blood tests.

The group sessions of the intervention group took place at the Holmlia Health Care Centre and the Church at Holmlia and were given in Norwegian and translated by a study-trained bicultural team worker.

The intervention group was divided into subgroups of 10-12 women. In all, nine groups were established. Each subgroup had six sessions on diet and lifestyle during the seven months of the intervention, and had the possibility to take part in a culturally adapted exercise program twice a week. Each session lasted about 1.5 hours. The first session began in April 2006, and the last in May 2008. The intervention model was based on the Cognitive Activation Theory of Stress (CATS) developed by Ursin and Eriksen (79). The model focuses on motivation and lack of motivation to engage in positive life style changes.

The dietary advice given in the individual counselling and group sessions was adapted to the Pakistani culture. They focused on increasing the intake of different types of foods that are part of the traditional Pakistani diet, which have been found to have a favourable effect on blood glucose and cholesterol, such as fruits and vegetables, and legumes. The women were also encouraged to eat more fish and change white flour products to whole meal products. In addition, there was an emphasis on sugar reduction and the intake and type of fat. Culturally adapted audio-visual materials were used as well as oral information. To reduce the chances of information leaking to the control group, no written information was given. Dialogue and feed back from the participants were encouraged in order to improve the sessions and the overall intervention. Part of the information material used in the sessions was taken from an information package for health care workers made by members in a reference group for the Norwegian Directorate of Health, regarding South Asian populations.

Culturally adapted physical program

The physical activity program consisted of low intensity exercise, such as walking groups. This was based on experiences and results from the “Diabetesverkstedet” and the MoRo-project. The goal was to increase the level of physical activity among the intervention subjects. The location of the exercise groups was set in close proximity to where the participants lived, as lack of availability has shown to be an important barrier to exercise (80).

The control group

The control group received general advice on diet and physical activity. They received these advices as they visited their doctor or the health care centre. Thus, the advices corresponded to the actual treatment offered to pre-diabetics and newly diagnosed diabetics in the primary health care. The control group was offered educational sessions after the post tests were completed.

2.3 Data collection methods

Much of the data for this thesis was collected and transferred for software systems by the project personnel before the commencement of this master thesis. The master student, Karianne Spetaas Johansen, was involved in the InnvaDiab project during the last part of the period, from January through May 2008. Her work was concentrated on the post test study, involving various parts of the data handling, such as transferring data from the questionnaires to the food database and software systems.

2.3.1 Dietary intake

Dietary intake was collected using two types of methods, FFQ and 2 X 48-hour recalls. The FFQ was given as an interview, carried out by trained staff at the time of inclusion at the Holmlia Health Care Centre. At this point an OGTT was taken, as well as a physical test. 48 hour recalls were carried out twice after the inclusion and post test were completed. There were in all seven female interviewers involved in the intervention. Mainly two of these women were in charge of most of the interviews. They managed Urdu and/or Punjabi, in addition to English and Norwegian and had insight in traditional foods.

2.3.2 The questionnaire

The FFQ approach asks study subjects to report their usual frequency of consumption of different foods for a specific period. The FFQ in the InnvaDiab project allowed team members to study the intake of each participant during the last few days, weeks or month. The questionnaire included 20 food groups, representing the main sources

of energy, fat, carbohydrates and sugar. In order to estimate relative nutrient intakes, the FFQ also contained questions regarding portion sizes.

The FFQ used in the InnvaDiab study was based on earlier studies conducted in Norway (13;17;20) as well as DE-PLAN, an international diabetes study, DE-PLAN (21). The food frequency questions used in the HUBRO were validated for ethnic Norwegians and modified to the Pakistani population (25). The dietary questions from the DE-PLAN have been validated for the Finnish population (21).

To improve the reporting of portion sizes, the InnvaDiab provided photos of certain types of foods, so that the respondents could easily point out the size of the portion by looking at the photos. The pamphlet "Bildehefte med porsjonsstørrelser" was developed by the Norwegian Food Safety Authority, the Norwegian Directorate of Health, and Department of Nutrition at the University of Oslo. In the FFQ it was used to estimate intake of drinks and amount of oil used in curry/salen. In addition, the selected pictures from "Matmalen", developed by the Swedish National Food Administration, were used.

Intention to change

Questions related to stages of change in consumption of vegetables, legumes, fruits, fat, and intake of sugar and white flour from the pre- and post questionnaires, were used to measure the intentions to change before and after the intervention. This was carried out by using the Stages of Change construct from the Trans Theoretical Model (TTM). This model is normally used to find an appropriate intervention model. However, it has also been used to study changes in motivation (73-75). In this master thesis it was used as a tool to look at differences in stages of change between baseline and post test, and at differences between the control group and intervention group.

Perceptions and knowledge of healthy and unhealthy dietary behaviour

The participants were also asked questions concerning what types of foods they thought would be beneficial and not in the prevention of DM2, what other factors that

could increase the risk of DM2, and what foods they perceived as healthy and unhealthy.

2.4 Data handling

Data was manually transferred from the forms to the appropriate computer programs; "The Statistical Package for Social Sciences" (SPSS) version 16.0 and Microsoft Office Excel 2003.

Statistical analyses

SPSS version 16.0 was used to explore and describe data and characteristics of the sample, by using frequency tables, estimation of means and medians with corresponding confidence intervals and/or percentiles. Most of the data analyzed in this master thesis was not normally distributed. Even by log-transforming the variables, it did not improve distribution by much. In order to use parametric techniques, it is assumed that the samples are normally distributed (7). Thus, a combination of parametric and non-parametric tests has been used. Paired t-tests were performed in order to estimate the mean scores for each group at baseline and post test. Differences in medians were tested by performing the Wilcoxon Signed Rank Test. After estimating changes in intake, the differences in medians between the control and intervention group were found by performing the Mann Whitney U-test. Chi-squared tests were performed to determine differences in categorical variables between the groups, while the McNemar's test was used to study differences in correlated proportions of baseline and post test data.

Outliers were kept in all analyses. Unless the value is mistakenly entered or the individual has an extreme value due to illness, it should not be altered (81). Missing values were coded as 9.0, 9.9 or 9.99 and were not included in the analyses. A significant level of 5% was chosen for the analyses.

Processing data from the food frequency questionnaire

The foods that were focused on in the group sessions were chosen for data analysis in this master thesis. These include vegetables, fruits and fruit juice, potatoes, legumes,

fish (fatty and lean), foods rich in fat and sugar (sweet bakery items, fast food and deep fried foods, sugar, honey and sweets), and different types of drinks (with and without added sugar). In addition, the intake of vitamins and cod liver oil was estimated. Several questions were also studied in order to give sufficient information on the women's intake of fat rich foods. Questions 3-7, 9-12, 13f, 15-19 and 21 (see Appendix 1) were used from the FFQ.

Intake of vegetables, fruits and fruit juice

In the FFQ, the intake of fruits and vegetables was measured by a set of five categories: 1) ≥4 portions/day, 2) 2-3 portions/day, 3) 1 portion/day, 4) 4-6 portions/week, 5) 1-3 portions/week, and 6) <1 portion/week. Fruit juice intake was categorized into 1) ≥4 glasses of juice/day, 2) 2-3 glasses/day, 3) 1 glass/day, 4) 1-6 glasses/week, and 5) Rarely/never. The Norwegian Directorate of Health (56) recommends five portions of fruits and vegetables per day (three portions of vegetables and two portions of fruits). Thus, we wanted to use the recommended intake of vegetables and fruits as cut-off points for the analyses. However, few of the participants in both baseline and post test reported such an intake of vegetables (7% and 5% for control and intervention respectively at baseline). This did not meet the criteria for many of the analyses. However, aggregating into: 1) ≥1 portion/day and 2) <1 portion/day, gave a higher percentage in each group which was sufficient for later analyses. In order to compare fruits and vegetables, the same categories were used for fruits.

In order to estimate the portion sizes of fruits and vegetables, examples were given in the questionnaire which corresponds to the recommendations by the Norwegian Directorate of Health. The collected intake of fruits, vegetables and fruit juice was converted into grams per day, by multiplying the average number of portions with the portion size. One portion is 150 grams of fruits or vegetables. Each of the five categories was converted into grams. The following estimations of intake were performed: 1) 600 g/day, 2) 375 g/day, 3) 150 g/day, 4) 107 g/day, 5) 43 g/day, and 6) 21 g/day.

Regarding estimation of intake of fruit juice, the pre coded questionnaire estimated 3 glasses to equal 0.5 litres. Intakes were converted to portions of fruits per day, as 1.5 dl fruit juice equals one portion of fruit (56). The categories were as follows: 1) 4.5 portions of fruit per day, 2) 3 portions per day, 3) 1 portion per day, 4), 0.5 portions per day, and 5) Nil. These were then converted into grams of fruits per day.

Legumes

Based on the information given in the questionnaire, the intake of legumes was calculated into decilitre (dl) per week. Here, one portion was equal to ½ katori. 1 katori equals 1 dl. Based on this, intakes were estimated and categorized into: 1) 14 dl/week, 2) 8.75 dl/week, 3) 3.5 dl/week, 4) 2.5 dl/week, 5) 1 dl/week, and 6) ≤ 0.5 dl/week.

Fat intake

Fat intake was estimated by several questions. In the first question, the women were asked what type of fat that was most commonly used at home. The categories were 1) Mainly oil or soft margarine, 2) Mainly margarine with plant sterols (Provita), 3) Mainly butter, 4) Do not use fat, and 5) Do not cook. As the mean proportion of category 1 was 73.5% at baseline and 90% at post test, it was not possible to rank the subjects. One question was related to what kinds of fat they used for different purposes (on Norwegian bread and chapatti, to prepare Paratha, in deep-fry, in curry/salen, and for other cooking purposes). The five categories were: 1) Butter, 2) Margarine, 3) Oil, 4) Ghee, and 5) Nothing.

Fat intake was further estimated from the question regarding how much and how often they usually bought oil, margarine, butter, and ghee. For each of the four, fat purchase was calculated into grams per week and grams per month. The amount of fat was estimated as follows: 1 litre of oil = 900 grams of fat, 1 kg of butter = 820 grams of fat, 1 kg of margarine = 800 grams of fat. Ghee was reported in kg and litres. 1 litre was estimated to 950 grams of ghee. 1 kg of ghee = 998 grams of fat (based on data from KBS). The participants reported the frequency per day, per week or per month. 1 month = 30 days = 4.29 weeks, and 1 week = 0.23 month. In Microsoft Office Excel, the respectively amounts of fats were added to estimate the

total of fat purchased. Statistical analyses have only been performed with regard to the purchase of oil, as this is their main source of fat; however, the purchase of other types of fat has been mentioned in the results and discussion.

A final estimate of fat was based on the question regarding how much oil they used when preparing curry/salen. This was usually reported by using photos from "Bildehefte med porsjonsstørrelser", where mug sizes were given as 150 g, 170 g, 200 g, and 260 g of oil. The participants also reported how many people they cooked for, and from this, grams of fat used when preparing this dish, were estimated.

Intake of drinks with and without sugar

Intake of soda with and without sugar, fruit drinks with sugar and whole fat milk and yoghurt was estimated in decilitre (dl) per week. The pre coded questionnaire estimated 3 glasses to equal 0.5 litres. From this, a daily intake was calculated. The total intake of whole fat milk and yoghurt also involved the participants' reported intake of how much whole fat milk they used in tea.

Intake of vitamins and cod liver oil

To assess the intake of supplements, the respondents were to answer according to four categories: 1) No, 2) Yes, every day, 3) Yes, sometimes, and 4) Yes, in the winter time. In cross tables, assumptions were not met, thus, a new variable was computed: 1) Daily and 2) Not daily.

Intake of other food items

Data on intake of fish, white bread and foods high in fat and sugar was also analyzed. Fish was pre coded as portions per week, while foods high in fat and sugar were converted from the original categories into portions per week. These included fast food and deep fried foods, and sweet bakery goods, ice cream, chocolate and pudding (referred to as "sweet bakery goods" in this thesis). In addition, the categories were also aggregated into a dichotomous variable: 1) Daily intake and 2) Not daily intake. White bread was estimated in grams per week and based on reported intake of white bread (Norwegian bread, naan, chapatti and paratha).

Processing data from questions on intention to change food intake

To obtain information about intention to increase consumption of fruits, vegetables, legumes, to reduce amount of fat, sugar, and white flour, and change type of fat used, the stages of change questions (questions 23 and 24 a-e, see Appendix 1) gave the participants five categories to choose from: 1) Pre-contemplation: "I have not changed behaviour the last 6 months, and I am not planning to for the next 6 months", 2) Contemplation: "I have not changed behaviour the last 6 months, but I am considering doing so within the next 6 months", 3) Preparation: "At the moment I am trying to change my behaviour, but not on a regular basis", 4) Action: "During the last 6 months, I have changed my behaviour", and 5) Maintenance: "I changed my behaviour more than 6 months ago". ("Behaviour" refers to the desired dietary changes mentioned above.) The categories have been aggregated to: 1) Pre action (stages 1-3) and 2) Action (stages 4 and 5).

Processing data from questions on knowledge and perceptions of healthy eating

When mapping the risk factors for DM2, the participants were asked: "Do you know of any factors that could increase the risk of developing diabetes?" This was an open-ended question (question 37, see Appendix 1) and the respondents were expected to mention as many factors as possible. As they responded, the interviewer registered the answers into 9 pre-coded categories: too little physical activity, overweight, family history of diabetes, stress, eat too much sugar, eat too much fat, certain foods/drinks, and other.

Perceptions of healthy eating were assessed by two questions: "What foods do you perceive as healthy/unhealthy?" These were open-ended questions where the interviewer marked the categories the respondent mentioned in the pre coded questionnaire (questions 28 and 31, see Appendix 1). In the question related to unhealthy foods, the following categories were pre-coded: saturated fat (animal fat), fat in general, sugar, white flour, polished rice, rice in general, too much oil, other, and do not know. For healthy foods, the following categories were in the pre-coded questionnaire: heavy/filling foods, lots of vegetables, meat, fish, proteins, oil/fat, lean

foods, carbohydrate rich foods (rice, bakery goods), sugar, depends (e.g. Ayurveda, cold/hot), water, and do not know. There were also options for "others" if the respondent mentioned other types of healthy or unhealthy foods.

Intention-to-treat and treatment received analysis

The intervention consisted of six teaching lessons. The analyses presented in the tables and figures are intention-to-treat (ITT) analyses. These analyses compare participants in the groups to which they were originally assigned (5) and include all participants in the intervention group, whether they showed up for six classes or none. In order to study the differences among those who received a certain level of information compared to the control group, treatment received analysis (TRA) was performed. In order to include participants in these analyses, the cut-off point for the number of classes attended was set to 60 % or above (4 or more classes out of 6). This cut-off point was decided after discussion within the research group. 60 women met these criteria and were included in the TRA, together with 96 women of the control group. One participant in the control group attended 5 teaching sessions and has been included in the "as treated" group for this part of the results. 9 of the women, who have been included in the ITT analyses, did not attend any classes at all.

2.4.2 Ethics

The study is conducted in full accordance with the ethical principles as per the World Medical Association Declaration of Helsinki. The Norwegian Data Inspectorate approved the study and it has been cleared by the Regional Committee for Medical Research Ethics.

3. Results

3.1 Participant profile

The demographic – and socioeconomic profiles of the participants are shown in Table 1. Most of the women had lived permanently in Norway after arrival, but the number of years in Norway varied greatly. It ranged from 1 to 33 years in the control group, and from 0 to 35 years in the intervention group. The educational level in the two groups was quite similar; a high proportion reported to have no formal education. The majority of the women had completed higher secondary, while 12.0% and 19.8% had studied at University or University College. Only 1 out of 5 women in the control group and 1 out of 4 in the intervention group reported their Norwegian language skills to be good or very good. Most women were married and had children. The mean number of children in both groups was between 3 and 4.

The participants' characteristics with regard to BMI and physical activity are shown in Table 2. The prevalence of overweight was very high in both groups. Obesity was present in 40.1% in the control group and 39.5% in the intervention group. The Asian specific cut-off points for BMI help to identify those at increased risk for DM2 and CVD in this population (35). A BMI of 23.0 – 27.5 kg/m^2 classifies Asian populations at increased risk for developing these conditions, while with a BMI ≥ 27.5 kg/m^2 people are at high risk. When applying these cut-off points, over 60% of the participants in both groups were at high risk.

Half of the women in the control group reported to be physically active (≥ 30 minutes of physical activity per day). The median time spent on physical activity was 10 minutes per day. In the intervention group even less women (37.4%) reported to be physically active daily. The median time for physical activity was 12.8 minutes per day.

Table 1: Baseline demographic – and socioeconomic status of the participants in control and intervention groups

	Control group		Intervention group	
	n (%)	Mean (95% CI))	n (%)	Mean (95% CI)
Age (n = 97, 99)[1]		41.5 (39.8, 43.1)		41.0 (39.3, 42.6)
Years in Norway (n = 94, 98)		15.2 (13.6, 16.7)		14.1 (12.5, 15.7)
Permanent in Norway (n = 92, 98)	80 (87.0)		84 (85.7)	
Formal education (n = 92)				
- Years of education (n = 92, 96)		8.9 (8.0, 9.8)		9.1 (8.2, 10.1)
- no formal education	9 (9.8)		13 (13.5)	
- middle school or less (≤ 7 years)	15 (16.3)		13 (13.5)	
- higher secondary (7-12 years)	57 (61.2)		51 (53.1)	
- University or College University	11 (12.0)		19 (19.8)	
Norwegian language skills (n = 96, 99)				
- very good	9 (9.4)		7 (7.1)	
- good	10 (10.4)		17 (17.2)	
- average	37 (38.5)		26 (26.3)	
- poor	24 (25.0)		30 (30.3)	
- very poor	16 (16.7)		19 (19.2)	
Marital status (n = 96, 98)				
- married	87 (90.6)		93 (94.9)	
- divorced/separated	6 (6.2)		4 (4.1)	
- widow	3 (3.1)		1 (1.0)	
Number of children (n = 95, 99)		3.3 (3.0, 3.7)		3.6 (3.3, 3.9)
- no children (n = 96, 99)	5 (5.2)		4 (4.0)	
Number of people in the household (n = 94, 93)		5.4 (5.0, 5.8)		5.6 (5.3, 6.0)

[1] Number of participants, n, in the control and intervention group respectively

Table 2: Baseline characteristics of participants in control and intervention groups

	Control group		Intervention group	
	n (%)	Mean (95% CI))	n (%)	Mean (95% CI)
BMI kg/m^2 (n = 97, 99)[1]		29.8 (28.7, 30.9)		29.5 (28.3, 30.6)
- normal weight (BMI 18.5 – 24.9)	16 (16.5)		23 (23.2)	
- overweight (BMI 24.9 – 29.9)	42 (43.3)		37 (37.4)	
- obese class I (BMI 30.0 – 34.9)	27 (27.8)		26 (26.3)	
- obese class II (BMI 35.0 – 39.9)	8 (8.2)		7 (7.1)	
- obese class III (BMI ≥ 40)	4 (4.1)		6 (6.1)	
At increased health risk (n = 97, 99)[2]				
- increased but acceptable risk (BMI 18.5 – 23.0)	4 (4.1)		6 (6.1)	
- increased risk (BMI 23.0 – 27.5)	33 (34.0)		33 (33.3)	
- high risk (BMI ≥ 27.5)	60 (61.9)		60 (60.6)	
Physically active[3] (n = 95, 99)				
- yes	48 (50.5)		37 (37.4)	
- no	47 (49.5)		62 (62.6)	
- minutes per day		26.9 (19.9, 34.0)		15.8 (10.8, 20.7)

[1] Number of participants, n, in the control and intervention group respectively

[2] The WHO Expert Consultation Group has recommended the use of Asian-specific cut-off points for BMI in order to identify those at increased health risk (35)

[3] ≥ 30 minutes of physical activity per day

3.2 Perceptions of the relationship between food and health at baseline and post test

3.2.1 What foods do they consider unhealthy and healthy?

To measure the participants' perceptions of healthy and unhealthy eating, they were asked to list foods they characterized as such. These were two open-ended questions posed to the participants. Some of the anticipated answers were pre coded in the questionnaire. When one of the pre coded categories was mentioned, the interviewer registered this in the form. If another than the pre coded food items was mentioned, the interviewer wrote this down in the options marked "other".

Table 3 shows the percentage of women that mentioned the different items they considered unhealthy at baseline and post test. The majority mentioned *sugar* and *too much oil*, while *white flour* was also mentioned by many. *Saturated fat* was only mentioned by about 1/3. Looking at the difference in proportions at baseline and post test within each group, significantly higher proportions were found at post test for the intervention group with regard to *sugar* and *white flour*. Regarding the fat variables, there were hardly any differences between baseline and post test. Baseline statistics (results not shown), showed no significant difference between the control and intervention group. At post test however, there was a significant difference between the control and intervention group with regard to white flour ($p = 0.003$). For *polished rice,* a higher, but only borderline significant, percentage was found for the intervention group ($p = 0.053$). For most of the variables, there were increased respondent rates at post test, however no significant differences were observed.

2-3% answered they did not know of any unhealthy foods, while for the category *other*, the replies were similar at baseline and post test. The majority mentioned *soda*, *pasta*, *rice, fast food, potatoes,* and *meat.*

Table 3: Foods and nutrients classified as unhealthy at baseline and post test, n = 71 (control), n = 75 (intervention)

Variable		Baseline (%)	Post test (%)	Within groups P-value[1]	Between groups post test P-value[2]
Saturated fat	Control	35.5	32.9	1.000	0.480
	Intervention	42.7	39.7	1.000	
Fat in general	Control	19.4	30.1	0.115	0.425
	Intervention	25.0	23.1	1.000	
Sugar	Control	65.6	79.5	0.281	0.843
	Intervention	64.6	82.1	0.019	
White flour	Control	23.7	26.0	1.000	0.003
	Intervention	28.1	51.3	0.009	
Polished rice	Control	6.5	11.0	0.109	0.053
	Intervention	14.6	24.4	0.473	
Rice in general	Control	6.5	8.2	1.000	0.880
	Intervention	7.3	10.3	0.581	
Too much oil	Control	60.2	64.4	0.864	0.331
	Intervention	60.4	55.1	0.627	

[1] McNemar's test for difference in correlated proportions of matched-pair samples (baseline and post test)

[2] Chi-square for 2X2 table (continuity correction) at post test

Table 4 shows what foods the participants classified as healthy foods at baseline and post test. As several of the pre coded food items were rarely mentioned, only food items mentioned by ≥10% are shown in the table. The majority of the participants considered *vegetables* and *fish* as parts of a healthy diet, and the proportions of responses at baseline and post test were quite similar. At post test, less than 10% mentioned *meat* as healthy, and the reduction in response rates for the intervention group was significantly different from baseline. Between group statistics showed no significant difference either at baseline or post test (results from baseline not shown). Only about 3% at baseline and post test replied *do not know*. Other responses were *whole wheat*, *chicken*, *limited salt*, *lentils*, and *fruits*.

Table 4: Foods classified as healthy at baseline and post test, n = 72 (control), n = 75 (intervention)

Variable		Baseline (%)	Post test (%)	Within groups P-value[1]	Between groups P-value[2]
Vegetables	Control	81.9	79.5	0.832	0.290
	Intervention	87.5	87.2	0.791	
Meat	Control	9.6	9.6	1.000	0.901
	Intervention	17.7	7.7	0.022	
Fish	Control	54.3	46.6	0.541	0.567
	Intervention	49.0	52.6	0.860	
Oil/fat	Control	18.1	13.7	0.302	0.132
	Intervention	9.4	6.4	0.754	

[1] McNemar's test for difference in correlated proportions of matched-pair samples (baseline and post test)

[2] Chi-square for 2X2 table (continuity correction) at post test

3.2.2 What factors do they consider to increase the risk of DM2?

Table 5 shows the percentage of women that mentioned the different factors they considered to increase the risk of DM2 at baseline and post test. The majority mentioned *too much sugar* as a risk factor. A significantly higher proportion in the intervention group mentioned *low level of physical activity* (significant also for the control group), *overweight, family with DM2*, and *too much fat* at post test than at baseline. There was no significant difference between the control and intervention group at baseline and post test (results from baseline not shown), however, there was a pronounced, but not quite significant difference between the groups regarding *family with DM2* ($p = 0.058$). At baseline, other factors specified were mainly food related, such as *flour, rice,* and *soda*. At post test, simple foods were also mentioned, but now there was more focus on eating habits and the quantity of foods. About 10% in both the control and intervention group could not mention one single risk factor for DM2 at baseline. This number had decreased to 4% in the control group and 2.5% in the intervention group at post test.

Table 5: Factors they consider to increase the risk of DM2 at baseline and post test, n = 71 (control), n = 78 (intervention)

Variable		Baseline	Post test (%)	Within groups P-value [1]	Between groups P-value [2]
Low level of physical activity	Control	30.1	53.5	0.001	0.191
	Intervention	28.9	65.4	0.000	
Overweight	Control	20.4	32.4	0.052	0.217
	Intervention	15.5	43.6	0.000	
Family with DM2	Control	21.5	18.3	1.000	0.058
	Intervention	14.4	33.3	0.009	
Stress	Control	30.1	42.3	0.210	0.756
	Intervention	26.8	39.7	0.248	
Too much sugar	Control	69.9	67.6	0.690	0.203
	Intervention	70.1	76.9	0.572	
Too much fat	Control	24.7	23.9	0.648	0.111
	Intervention	21.6	35.9	0.035	

[1] McNemar's test for difference in correlated proportions of matched-pair samples (baseline and post test)

[2] Chi-square for 2X2 table (continuity correction) at post test

3.3 Intention to change food intake at baseline and post test (stages of change)

In order to study if the intervention had any effect on the participants' intention to change food intake regarding specific foods, the stages of change construct was used. The questions involved intention to change consumption of fruits, vegetables, legumes, fat, sugar, and white flour, and type of fat. These were chosen as they were the foods that were mainly focused on in the teaching sessions. The stages of change classifies people into 5 stages: 1*) Pre-contemplation*: "I have not changed behaviour the last 6 months, and I am not planning to for the next 6 months", 2) *Contemplation*: "I have not changed behaviour the last 6 months, but I am considering doing so within the next 6 months", 3) *Preparation:* "At the moment I am trying to change my behaviour, but not on a regular basis", 4) *Action*: "During the last 6 months, I have changed my behaviour", and 5) *Maintenance:* "I changed my behaviour more than 6 months ago".

3.3.1 Intention to reduce fat intake

Figure 2 illustrates the distribution of participants at baseline and post test. At baseline, the groups were distributed more or less evenly around 20% from stages 1 through 5, except for contemplation for the control group and maintenance for the intervention group. This resulted in a non-significant difference between the control and intervention group at baseline. In the intervention group, there had been a shift of participants from the pre- contemplation and contemplation stages to the action stage. Some had also regressed from the maintenance stage. This occurred to a much lesser extent in the control group. As a result, there was a significant difference between the control and intervention group at post test ($p = 0.001$).

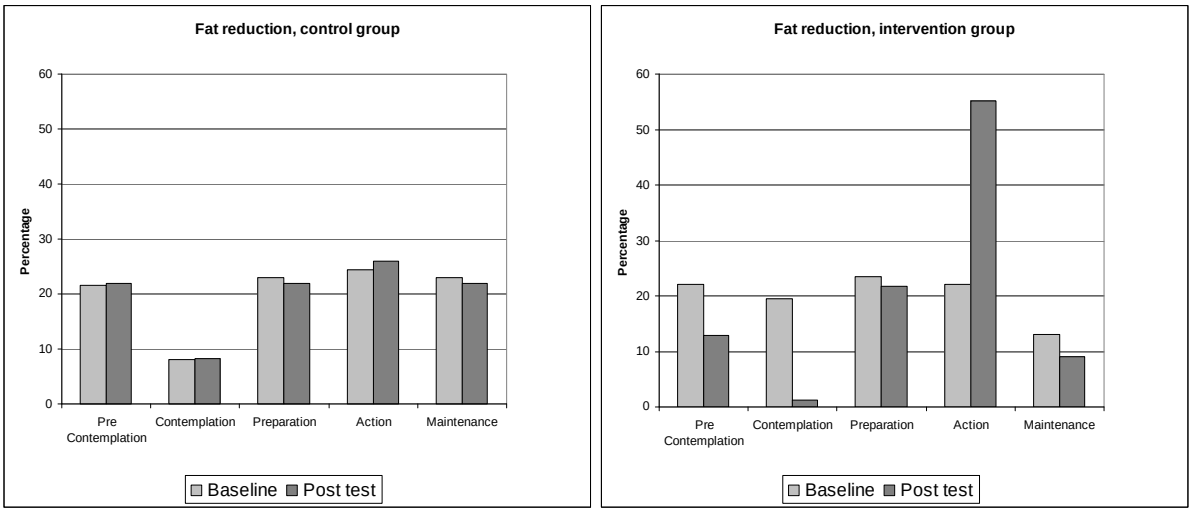

Figure 2: Percent participants in the different stages of change with regard to fat reduction in the control (n = 74) and intervention (n = 78) group at baseline and after 6 months. (Differences in proportions in the action stages at baseline and post test were significant in the intervention group ($p<0.001$). Difference between the control and intervention group was significant at post test ($X^2= 17.65$, $p = 0.001$))

In order to measure the difference in proportions of participants in the action stages at baseline and post test, McNemar test was performed. In the control group, 20.8% had moved from the pre action stages to the action stages (n = 15), while 18.1% (n = 13) had regressed to the pre action stages. 37.6% in the intervention group had moved into the action stages (n = 29), while 7.8% had moved back into the pre action stages (n = 6). A significant difference in correlated proportions was found for the intervention group ($p<0.001$) due to a higher proportion in the action stages at post test.

3.3.2 Intention to change type of fat

A stage of change classification was further measured with regard to the participants' intention to change the type of fat they used. Again, they were asked whether they had any intention to change the type of fat they were currently using, or if they might have changed already. The responses at baseline resulted in a U-shaped curve, with the majority in stages 1 and 5 and no significant difference between the control and intervention group (Figure 3). 21.6% and 15.6% in the control and intervention group respectively were in the action stage at this point. At post test, there had again been a

shift in respondents in the intervention group from the two first stages and the maintenance stage, into the preparation and action stages. A significant difference between control and intervention group was found at post test (p = 0.004).

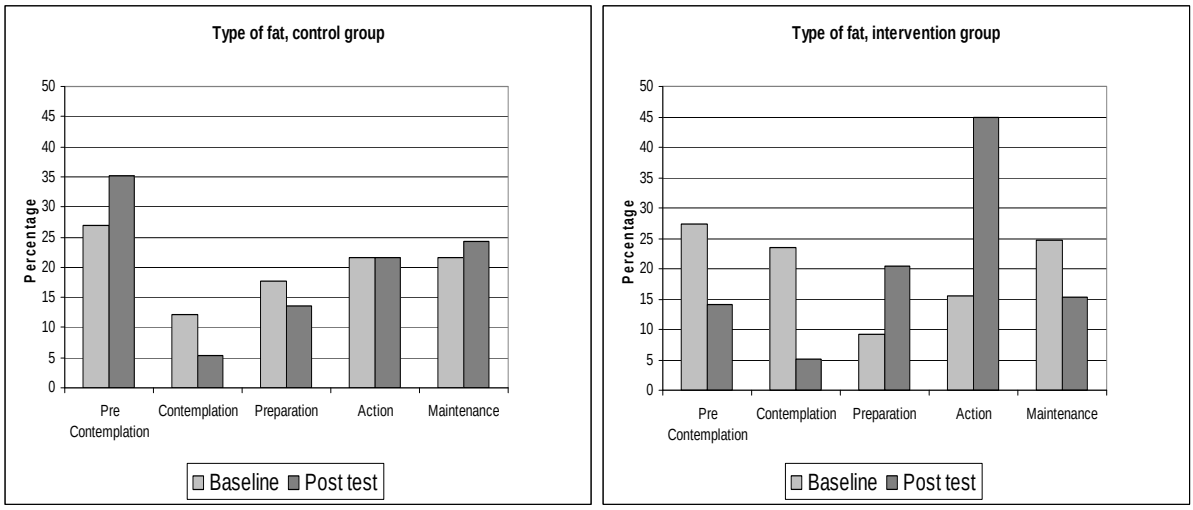

Figure 3: Percent participants in the different stages of change with regard to changing type of fat in the control (n = 74) and intervention (n = 78) group at baseline and after 6 months. (Differences in proportions in the action stages at baseline and post test were significant in the intervention group (p = 0.007). Difference between the control and intervention group was significant at post test (X^2= 15.65, p = 0.004))

McNemar's test showed a significant difference in correlated proportions for matched-pair samples for the intervention group (p = 0.007). 31.1% in this group had moved from the pre action to the action stages (n = 24), while 10.4% had regressed into pre action at post test (n = 8).

3.3.3 Intention to reduce sugar intake

The participants were also asked about their intentions to reduce sugar intake. At baseline, there was a steady increase from stage 1 through stage 4 in both groups (Figure 4). No significant difference between the control and intervention group was observed. At post test, 65.4% of the intervention group was in the action stage, while for the control group, 31.1% was in this stage. A significant difference was found between the control and intervention group at post test (p<0.001).

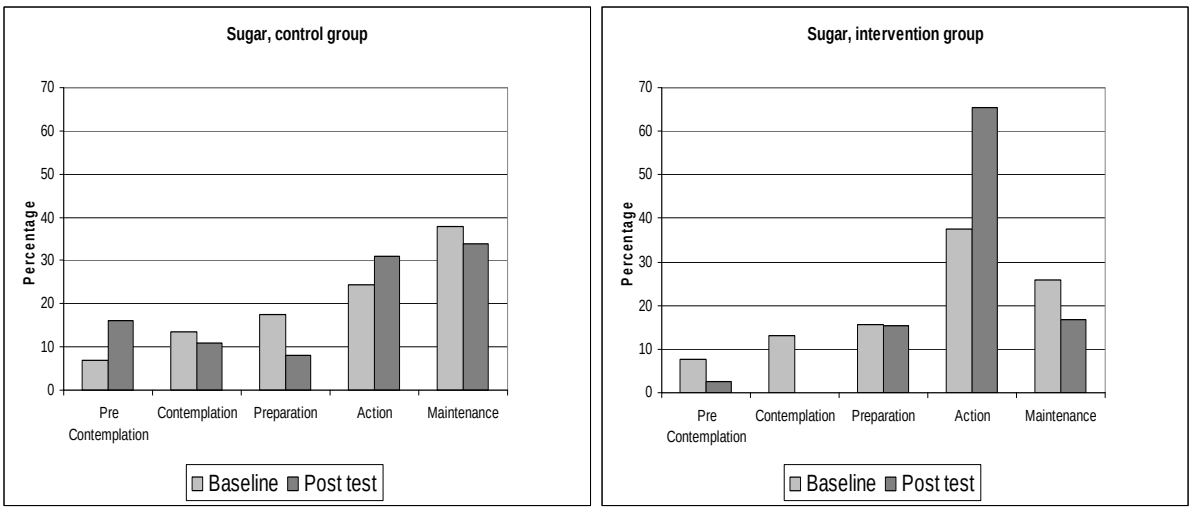

Figure 4: Percent participants in the different stages of change regarding motivation to reduce sugar intake in the control (n = 74) and intervention (n = 78) group at baseline and after 6 months. (Differences in proportions in the action stages at baseline and post test were significant in the intervention group (p = 0.009). Difference between the control and intervention group was significant at post test (X^2= 31.44, p<0.001))

There was a significant difference in correlated proportions of participants for the intervention group (p = 0.009). 26% had moved into the action stages at post test (n = 20), while 7.8% had moved from action to pre action (n = 6).

3.3.4 Intention to increase vegetable intake

In order to measure the participants' intentions to increase their intake of vegetables, they were asked if they had considered increasing their intake, or if they had already done so. Figure 5 shows the distribution between the control and intervention group and stages of change at baseline and post test. No significant difference was found between the control and intervention group at baseline. The results showed a more or less steady increase in responses from stages 1 through 5, except for the action stage in the intervention group, while in the control group, the preparation and maintenance stages were high compared to the other 3 stages. About 30% and 35% of in the control and intervention group respectively were in the maintenance stage. At post test, the distribution was more uneven. For the control group, there had been a shift in participants from contemplation into the action stage. In the intervention group however, the high increase in the action stage was due to a movement from all the

other stages, except for the preparation stage. A significant difference between control and intervention group was found at post test (p = 0.003).

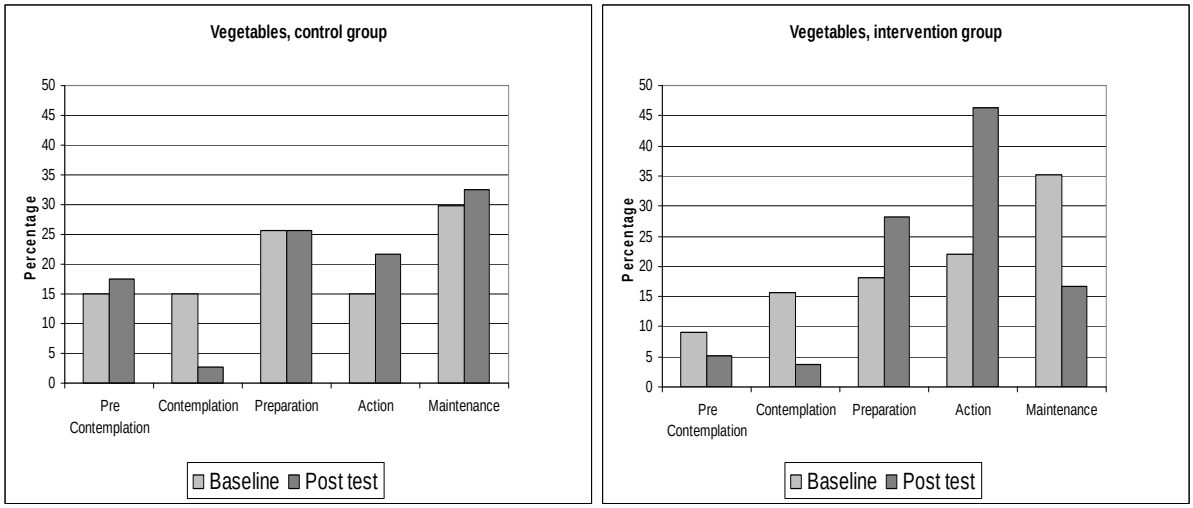

Figure 5: Percent participants in the different stages of change regarding motivation to increase vegetable intake in the control (n = 74) and intervention (n = 78) group at baseline and after 6 months. (Difference between the control and intervention group was significant at post test (X^2= 16.05, p = 0.003))

23.4% in the intervention group had moved from the pre action to action stages (n = 18), while 16.9% had moved from action to pre action (n = 13), however no significant difference in proportions was found.

3.3.5 Intention to increase intake of legumes

Questions related to the stages of change were then asked regarding intentions to increase legumes. As shown in Figure 6, at baseline, the two groups were quite similar at all stages, with the highest frequency in the maintenance stage. No significant difference between the control and intervention group was found. However, at post test, the distribution had changed. In the control group, most respondents were still in the maintenance stage, while for the intervention group, a movement from the pre-preparation stages and maintenance stage into the action stage was observed. A significant difference between the control and intervention group was found at post test (p = 0.019).

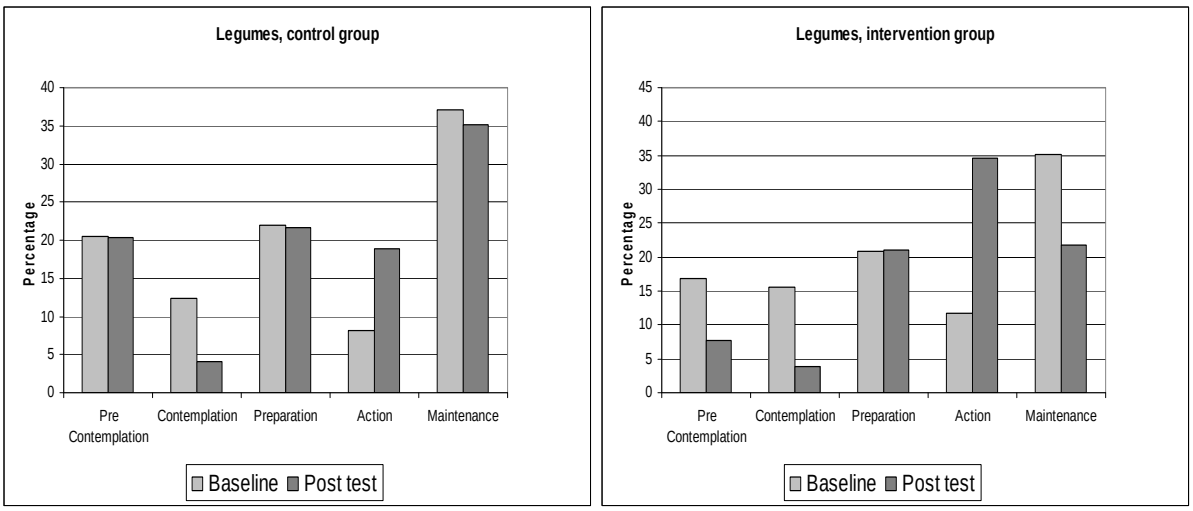

Figure 6: Percent participants in the different stages of change with regard to increase intake of legumes in the control (n = 73) and intervention (n = 78) group at baseline and after 6 months. (Difference between the control and intervention group was significant at post test (X^2= 11.74, p = 0.019))

There was no significant difference in proportions of matched-pairs in either group; however, there was a higher proportion of both the control and intervention group who had moved from the pre action to action stages than the opposite.

3.3.6 Intention to increase intake of fruits

In order to classify the participants into stages of change regarding fruit intake, they were asked about their intentions to increase the intake of this food group. Chi-square test showed no significant difference between the control and intervention group at either baseline or post test, even when aggregating the stages of change categories (results not shown). The percentage of the intervention group in the action stage increased from baseline to post test (10.7% versus 30.8%), while for the maintenance stage, the percentage went from 45.3% at baseline to 23.1% at post test. In the control group, the distribution was more even, except for a slight decrease in the maintenance stage from baseline to post test. There was no significant difference between baseline and post test within any of the groups.

3.3.7 Intention to reduce intake of white flour

The participants were asked about their intentions to reduce intake of white flour in order to classify them into stages of change. There was no significant difference between the control and intervention group at baseline. The distribution resulted in a U-shaped curve, with the highest frequencies of respondents in stages 1 and 5 in the control group, and 1 and 4 in the intervention group, as shown in Figure 7. At post test, a significant difference between the control and intervention group was observed ($p<0.001$). For the intervention group, the marked increase in the action stage, and to a lesser extent the preparation stage, was due to the movement of respondents from the three other stages, mainly pre-contemplation and contemplation.

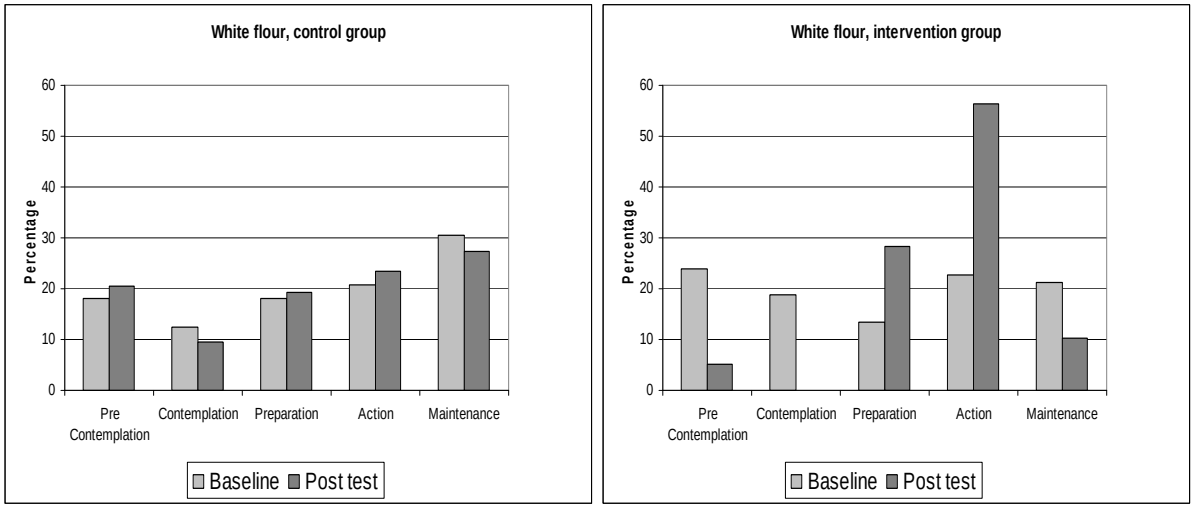

Figure 7: Percent participants in the different stages of change with regard to reduce intake of white flour in the control (n = 73) and intervention (n = 78) group at baseline and after 6 months. (Differences in proportions in the action stages at baseline and post test were significant in the intervention group ($p = 0.006$). Difference between the control and intervention group was significant at post test ($X^2= 32.11$, $p<0.001$))

There was no difference in correlated proportions in the control group. For the intervention group, 34.7% had moved from the pre action to the action stages (n = 26), and 12% had regressed into the pre action stages (n = 9). There was a significant difference between the proportions in the action stages from baseline to post test in the intervention group ($p = 0.006$).

3.4 Intake of foods and drinks at baseline and post test

3.4.1 Drinks with and without sugar

Table 10 shows the results from baseline and post test data regarding drinks with and without sugar. These results are estimated from the categories in the pre coded questionnaire, where 3 glasses equal 0.5 litres. From this, continuous variables were made in order to estimate median and mean intakes in decilitre (dl) per day or week.

A significant reduction in intake of soft drinks with sugar was found for the intervention group ($p<0.001$) and the difference in change of intake was significant between the control and intervention group ($p<0.001$). The change in intake of fruit drinks with sugar added was also significantly reduced in the intervention group ($p = 0.002$), and again the difference in change between the groups was significant ($p = 0.013$). Intake of whole fat milk and yoghurt had decreased in both groups from baseline to post test, but significance was only found for the intervention group ($p = 0.027$). However, the difference in change between the control and intervention group was not significant. The intake of soft drinks without added sugar was reduced in both groups; however, not significantly. Treatment received analysis (TRA) was then performed on the same variables only for those participants who had attended ≥ 4 out of the 6 classes offered to the intervention group, compared to the control group (results not shown). For both soft drinks and fruit drinks with sugar added, a significant reduction in intake was observed in the "as treated" group ($p<0.001$). The difference in change between the control and "as treated" group was also significant for both variables ($p<0.003$). There was no significant change with regard to whole fat milk and yoghurt.

Table 10: Intake of drinks with and without added sugar in the control and intervention group at baseline and post test

Variable	Group	Baseline Median (P25, P75)[1] Mean	Post test Median (P25, P75)[1] Mean	Within groups P value[2]	Between groups P value[3]
Intake of soft drinks With sugar (Dl/week)	Control (n = 73)	5.81 (0.0, 5.81) 4.4	5.81 (0.0, 5.81) 5.1	0.458	0.000
	Intervention (n = 75)	5.81 (0.0, 5.81) 5.0	0.0 (0.0, 5.81) 2.5	0.000	
Intake of soft drinks Without added sugar (Dl/week)	Control (n= 73)	0.0 (0.0, 0.0) 2.0	0.0 (0.0, 5.81) 1.8	0.858	0.384
	Intervention (n = 77)	0.0 (0.0, 0.0) 1.3	0.0 (0.0, 0.0) 1.0	0.403	
Intake of fruit drinks Sugar added (Dl/week)	Control (n = 71)	0.0 (0.0, 0.0) 1.2	0.0 (0.0, 0.0) 1.3	0.853	0.013
	Intervention (n = 76)	0.0 (0.0, 5.81) 2.3	0.0 (0.0, 0.0) 0.8	0.002	
Intake of whole fat milk and yoghurt (Dl/day)	Control (n = 42)	2.15 (1.30, 4.05) 3.0	1.79 (1.08, 3.02) 2.3	0.231	0.709
	Intervention (n = 50)	2.03 (1.08, 3.03) 2.9	1.35 (1.06, 2.14) 2.0	0.027	

[1] P25 = 25th percentile, P75 = 75th percentile
[2] Wilcoxon's signed rank-sum test
[3] Mann – Whitney U Test for difference in change between intervention group and control group

3.4.2 Foods rich in fat and sugar

In order to measure the changes in intake of foods rich in fat and sugar, the categories in the pre coded questionnaire were converted into portions per week. As Table 11 illustrates, there were few changes in intake from baseline to post test. For the control group, the increased intake of sweet bakery goods was significant ($p = 0.022$). There was no significant difference in change between the groups.

The variables were also aggregated into a dichotomous variable: 1) ≥ 1 portion a week of and 2) < 1 portion per week (results not shown). Even at this point, no significance was observed between the control and intervention group for any of the variables. For fast food, the highest frequency of respondents reported an intake of 1-3 times per month. The percentage with an intake of ≥ 1 portion a week of fast food in the control group was reduced from 44.7% at baseline to 36.5 % at post test, while it was reduced from 37.4% to 30.7% in the intervention group. Regarding deep fried foods, the percentage of participants who had an intake of ≥ 1 portion a week, was reduced from 27.4% to 21.3% and 26.2% to 23.1% in the control group and intervention group respectively.

Sweet foods were dichotomized into 1) Daily intake and 2) Not daily intake. The daily intake of sweet bakery goods had increased in the control group, while it was reduced in the intervention group (results not shown). There was no significant difference between the groups. Regarding intake of sugar, honey and sweets, the daily intake was reduced in the intervention group (from 9.1% to 3.9%), however, not significantly, while it increased in the control group (results not shown).

Table 11: Intake of foods rich in fat and sugar in the control and intervention group at baseline and post test

Variable	Group	Baseline Median (P25, P75)[1] Mean	Post test Median (P25, P75)[1] Mean	Within groups P value[2]	Between groups P value[3]
Fast food (Portions per week)	Control (n = 72)	0.5 (0.5, 2.0) 1.3	0.5 (0.5, 2.0) 1.2	0.308	0.483
	Intervention (n = 78)	0.5 (0.5, 2.0) 1.1	0.5 (0.5, 2.0) 1.1	0.673	
Deep fried foods (Portions per week)	Control (n = 74)	0.5 (0.3, 2.0) 1.0	0.5 (0.25, 0.5) 0.8	0.129	0.812
	Intervention (n = 78)	0.5 (0.5, 2.0) 1.1	0.5 (0.3, 0.5) 0.9	0.439	
Sweet bakery goods (Portions per week)	Control (n = 73)	2.0 (1.0, 7.0) 3.5	2.0 (2.0, 7.0) 4.5	0.022	0.147
	Intervention (n = 78)	2.0 (2.0, 7.0) 3.6	2.0 (2.0, 7.0) 3.9	0.607	
Sugar, honey, sweets (Portions per week)	Control (n = 74)	1.0 (1.0, 1.0) 1.8	1.0 (1.0, 2.0) 2.0	0.404	0.100
	Intervention (n = 77)	1.0 (1.0, 2.0) 1.9	1.0 (1.0, 2.0) 1.6	0.182	

[1] P25 = 25th percentile, P75 = 75th percentile
[2] Wilcoxon's signed rank-sum test.
[3] Mann – Whitney U Test for difference in change between intervention group and control group

3.4.3 Fruits and vegetables, legumes, potatoes, and white bread

In order to estimate daily intake of fruits and vegetables, the categories in the pre coded questionnaire were converted into grams per day as described in the methods section. Intake of legumes was estimated in dl per week, while potatoes were estimated in number of potatoes consumed per week. Intake of white bread was estimated from intake of white flour products and converted into grams per week.

Table 12 shows baseline and post test intake of fruits, juice and vegetables, legumes, potatoes and white bread in the control and intervention group. Intake of fruits, fruit juice and vegetables had increased with 48.7 g from baseline to post test in the intervention group ($p = 0.031$). There was no significant change in the control group. The intake of legumes had increased in both groups, however this was not significant. The number of potatoes consumed per week had decreased in both groups, but this was not significant. The intake of white bread had decreased in the intervention group, however, not significantly. In the control group, there was an increased intake of white bread. The difference between the control and intervention group was not significant.

The daily intakes of fruits, fruit juice and vegetables respectively, had increased in both the control and intervention group from baseline to post test. None of these were significant when analyzed one by one. TRA was performed on these variables (results not shown). The intake of fruit, fruit juice and vegetables had increased with 85 g in the “as treated” group ($p = 0.001$). No significant difference between baseline and post test was found for the control group. The difference between the control and “as treated” group was significant ($p<0.001$). For legumes and potatoes, only very minor differences in intake were observed compared to the analyses performed on the intention to treat (ITT) group.

Table 12: Intake of fruits and vegetables, legumes, potatoes and white bread in the control and intervention group at baseline and post test

Variable	Group	Baseline Median (P25, P75)[1] Mean	Post test Median (P25, P75)[1] Mean	Within groups P value[2]	Between groups P value[3]
Fruits, fruit juice and vegetables (Grams per day)	Control (n = 75)	268.0 (193.0, 375.0) 306.2	300.0 (193.0, 450.0) 328.3	0.149	0.652
	Intervention (n = 78)	268.0 (161.0, 426.0) 326.7	300.0 (193.0, 493.0) 375.4	0.031	
Legumes (Dl per week)	Control (n = 74)	0.98 (0.98, 0.98) 0.94	0.98 (0.98, 0.98) 1.17	0.540	0.369
	Intervention (n = 78)	0.98 (0.98, 0.98) 0.99	0.98 (0.98, 0.98) 1.14	0.219	
Potatoes (numbers per week)	Control (n = 75)	2.0 (1.0, 3.0) 2.3	2.0 (1.0, 2.5) 2.0	0.119	0.483
	Intervention (n = 78)	2.0 (1.0, 2.5) 2.6	2.0 (1.0, 2.6) 2.1	0.384	
White bread (grams per week)	Control (n = 45)	90.0 (45.0, 95.0) 91.8	85.5 (45.0, 150.0) 113.6	0.706	0.797
	Intervention (n = 50)	52.5 (22.5, 100.0) 84.6	41.0 (22.5, 90.0) 73.6	0.453	

[1] P25 = 25th percentile, P75 = 75th percentile
[2] Wilcoxon's signed rank-sum test.
[3] Mann – Whitney U Test for difference in change between intervention group and control group

3.4.4 Fish

Intake of fish was measured as consumption of lean and fatty fish per week. These were then added together in order to estimate the total intake of fish per week. Table 13 shows that the intake of both lean and fatty fish was very low in both intervention and control groups at baseline. The intervention group had a small, but significant increase in the intake of lean fish from baseline to post test ($p = 0.040$), but the difference in change between the control and intervention group was not statistically significant. Both groups had increased the intake of fatty fish and fish in total, however, this increase was only significant for the control group. The mean intake of fatty fish was only about 0.5 dinner portion per week at post test. The TRA (results not shown) showed a few differences in results compared to those described above. The intake of lean fish was not significantly increased in the "as treated" group ($p = 0.063$). For the intake of fatty fish however, there was a greater increase in the mean from baseline to post test in the "as treated" group. However, this was not significant. The intake of fish in total had increased significantly in the "as treated" group ($p = 0.032$). In the control group, no changes were observed.

Table 13: Intake of fish in the control and intervention group at baseline and post test

Variable	Group	Baseline Median (P25, P75)[1] Mean	Post test Median (P25, P75)[1] Mean	Within groups P value[2]	Between groups P value[3]
Intake of lean fish (Portions per week)	Control (n = 74)	0.5 (0.0, 0.82) 0.48	0.5 (0.0, 1.0) 0.66	0.066	0.904
	Intervention (n = 76)	0.5 (0.0, 1.0) 0.50	0.5 (0.03, 0.75) 0.60	0.040	
Intake of fatty fish (Portions per week)	Control (n = 74)	0.0 (0.0, 0.5) 0.30	0.25 (0.0, 1.0) 0.50	0.023	0.845
	Intervention (n = 76)	0.38 (0.0, 0.75) 0.45	0.5 (0.0, 0.75) 0.54	0.176	
Fish total (Portions per week)	Control (n = 74)	1.0 (0.0, 1.0) 0.77	1.0 (0.0, 2.0) 1.11	0.009	0.446
	Intervention (n = 76)	1.0 (0.32, 1.0) 0.96	1.0 (0.5, 1.5) 1.14	0.090	

[1] P25 = 25th percentile, P=75 = 75th percentile
[2] Wilcoxon's signed rank-sum test
[3] Mann-Whitney U Test for difference in change between intervention group and control group

3.4.5 Oil

Intake of fat and type of fat was measured by several questions. In both groups, over 90% and 96% at baseline and post test reported to use oil or margarine respectively in food preparation. Ghee was only reported to be used by 1-3%, mainly in traditional dishes. Estimation of intake of oil was based on two questions in the pre coded questionnaire. One question was related to the amount of oil used when preparing curry/salen. The respondents were shown pictures of 4 mugs of different sizes, in order to make it easier to report the amount. The mugs were pre coded and converted into grams of oil, which was then used in these analyses. Another question asked the respondents to report how much and how often they bought oil. This amount was then converted into grams per month.

Table 14 shows that the amount of oil purchased per month was significantly reduced for both the control and intervention group, with a slightly greater reduction in the intervention group. The difference in change between the control and intervention group was not significant. The reported amount of oil used in salen/curry was reduced in the intervention group and increased in the control group. However, the changes were not significant. The TRA (results not shown) revealed only minimal differences in the amount of oil used in salen/curry compared to the results discussed above. Regarding the amount of oil purchased per month, the means at baseline and post test in the “as treated” group were higher compared to that shown in Table 14 (4497 and 3028 grams respectively), which was significantly different ($p = 0.008$). In the control group, only minor differences in amount of oil purchased were found compared to the ITT analysis.

Table 14: Consumption of oil in the control and intervention group at baseline and post test

Variable	Group	Baseline Median (P25, P75)[1] Mean	Post test Median (P25, P75)[1] Mean	Within groups P value[2]	Between groups P value[3]
Oil used in salen/curry (Grams per dish)	Control (n = 68)	100.0 (75.0, 150.0) 115.9	150.0(75.0, 150.0) 121.0	0.362	0.353
	Intervention (n = 71)	150.0 (75.0, 150.0) 119.3	132.0 (75.0, 150.0) 117.1	0.750	
Oil: Fat from oil purchased (Grams/month)	Control (n = 84)	3600 (2250, 6077) 4624.1	2616.5 (803.3, 4503.8) 3234.2	0.001	0.414
	Intervention (n = 65)	3600 (2250, 5148) 4276.0	1800 (0, 36664.3) 2536.2	0.000	

[1] P25 = 25th percentile, P75 = 75th percentile
[2] Wilcoxon's signed rank-sum test.
[3] Mann – Whitney U Test for difference in change between intervention group and control group

3.4.6 Cod liver oil and vitamin supplements

Regarding intake of cod liver oil, more participants in both the control and intervention group reported a daily intake after the intervention (see Figure 8). For the control group, 17.2% at baseline and 25.3% at post test reported to take cod liver oil every day. For the intervention group, the intake had increased from 12.2% to 17.9%. There was a significant difference between the groups at post test ($p = 0.027$). Results from the McNemar's test showed no significant difference of matched-pairs between baseline and post test for any of the groups.

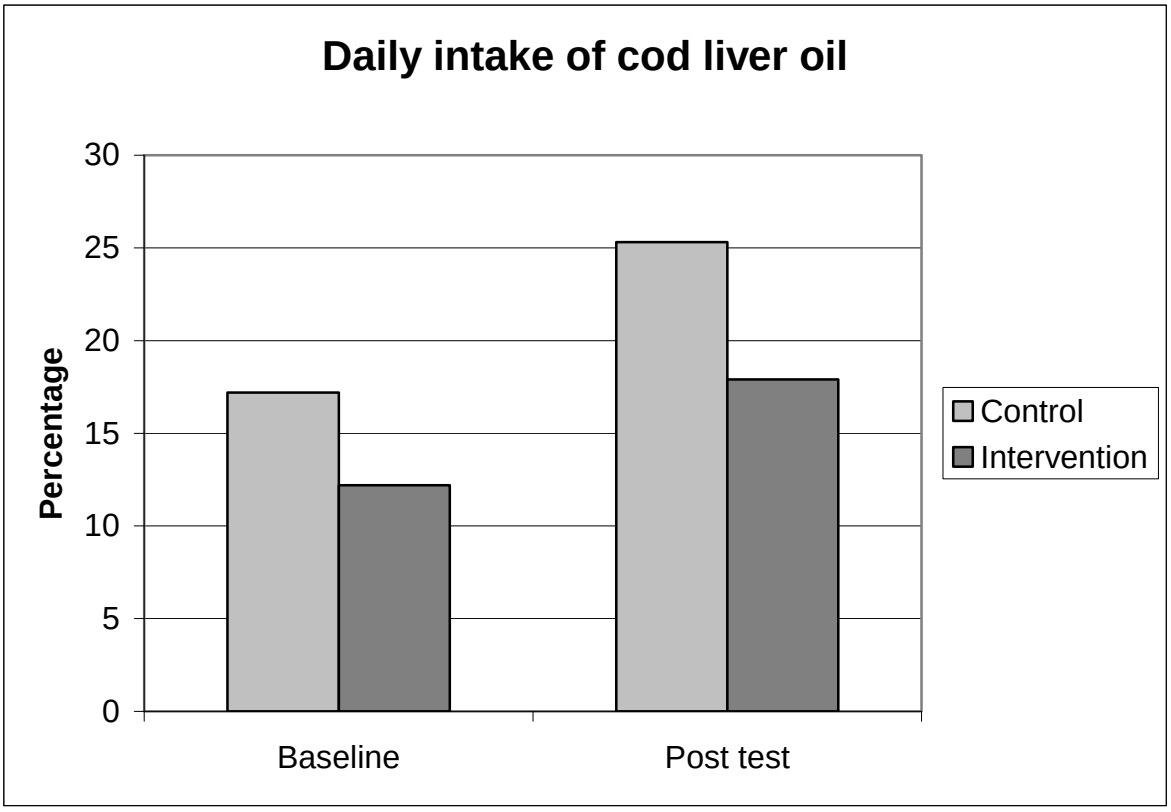

Figure 8: Daily intake of cod liver oil in the control and intervention group at baseline and post test. (Differences between groups were significant at post test ($X^2 = 7.23$, $p = 0.027$))

The daily intake of vitamins had increased from 27.7% to 33.8% for the control group. In the intervention group however, the percentage of participants who reported to take vitamins on a daily basis, had decreased from 21.4% to 17.9%. There was no significant difference between the groups at baseline. However, when aggregating to a dichotomous variable (daily/not daily), a significant difference between the control

and intervention group was observed at post test (p = 0.038). When looking at the proportions at baseline and post test, no significant difference was observed for any of the groups.

3.5 The relationship between intention to change and actual dietary change

In order to measure whether the reported change in intention resulted in actual change in intake, comparisons of change in intake of selected foods between groups characterised by their movement in the stages of change, were carried out. The participants were categorized into two groups: group 1) Those that had moved from the pre action stages to the action stages and group 2) those that had moved from the action stages to pre action stages or had not moved at all with regard to these. “Pre action” corresponds to the pre-contemplation, contemplation and preparation stages, and “action” corresponds to the action and maintenance stages. The change in intake from baseline to post test was calculated for the foods which were mentioned in the stages of change construct. Since the N was low after match with changes in intake, the intervention group and control group were added together in order to not loose too much power for these analyses. The results are presented in Table 15.

The weekly intake of fruits had increased by 2.1 portions in group 1, which was significantly higher than for group 2 (p = 0.004). Those who had moved from the pre action stages into the action stages, also reported a higher increase in intake of legumes than the rest of the participants (p = 0.015). The weekly intake of vegetables had increased by 2.2 portions in the group that had moved from the pre action to the action stages. This increase was greater than for group 2; however, this was not significant. Regarding intake of white bread, group 2 reported a greater increase in intake, compared to group 1 however, the difference between the groups was not significant.

The FFQ did not contain any questions to measure actual intakes of fat and sugar. Therefore, intake of sweet bakery goods was used as a proxy indicator for sugar

intake, while purchase of oil, was used as a proxy indicator for the fat intake. Intake of sweet bakery goods was reduced in group 1 and increased in group 2. This difference was not significant. Regarding the purchase of oil, group 1 reported a greater reduction in amount purchased, than group 2, however, this difference was not significant.

Table 15: Changes in dietary intake among women who moved from the pre action to action stages (group 1) and those who did not move, or regressed to pre action (group 2)

Food	Group 1 Mean Median (P25, P75)[1]	Group 2 Mean Median (P25, P75)[1]	Between groups P[2]
Change in:			
Vegetables (portions per week) (gr. 1 n = 53, gr. 2 n = 197)	2.2 0.0 (0.0, 2.0)	2.0 0.0 (-1.5, 2.0)	0.090
Fruits[3] (portions per week) (gr. 1 n = 42, gr. 2 n = 102)	2.1 1.0 (0.0, 5.0)	0.1 0.0 (-2.0, 1.25)	0.004
Legumes (dl/week) (gr. 1 n = 53, gr. 2 n = 96	0.4 2.0 (2.0, 2.0)	0.1 2.0 (2.0, 2.0)	0.015
White bread (grams per week) (gr. 1 n = 40, gr. 2 n = 53)	3.0 9.3 (-31.0, 64.6)	20.4 0.0 (-22.5, 29.3)	0.797
Sweet bakery goods (portions per week) (gr. 1 n = 48, gr. 2 n = 101)	-0.2 0.0 (-1.0, .075)	0.7 0.0 (-1.0, 3.0)	0.263
Oil purchased (grams per month) (gr. 1 n = 56, gr. 2 n = 56)	-1294 -607 (-2250, 9.75)	-770 -176 (-1490, 863)	0.200

[1] P25 = 25th percentile, P75 = 75th percentile
[2] Mann – Whitney U Test for difference between group 1 and group 2
[3] Fruit juice not included

4. Discussion

4.1 Discussion of methods

4.1.1 Data sampling and randomization

Studies have shown that reaching South Asians, and especially women in this group, with regard to health information and health education, is challenging due to several factors: illiteracy, low level of education and poor Norwegian language skills. Furthermore, restrictions imposed on the women by their families with regard to going out alone or talking to health workers of the opposite sex without a chaperon present, also make it harder to reach this group. In addition, they may have different health beliefs and behaviours than people in the host country. Thus, South Asians are often excluded from trials due to the increased cost and time associated with their inclusion, especially because of the language barriers.

In order to reach this population, a multi-recruitment strategy has been recommended (82). A British study of South Asians (82), recommended, in addition to the multi-recruitment strategy, to follow certain strategies for recruitment of South Asians, which has been used in the InnvaDiab study: define the demographic and social profiles of the population to be included, consult representative community members to provide assistance in the study, and set eligibility criteria as wide as possible. In addition, the British study recommends the use of focus groups to identify any potential barriers.

In order to increase internal and external validity, quantitative researchers often work with large, randomly selected samples. Quantitative researchers working with survey results aim at generalising their descriptive information from their sample back to the parent population based on similarities in the demographics of the groups (83). The InnvaDiab sought to study the selected participants in the control and intervention group as a representation of all Pakistani women in Oslo, so that the findings and conclusions drawn could be applied to the rest of the Pakistani community. However,

since random sampling was not used, certain challenges do arise, such as selection bias and recruiting subjects who are more motivated or want to learn more about nutrition or their own health status. Thus, it is not certain that the participants are statistically representative of their population (83). Random sampling ensure generalizability (84), guaranteeing that each unit of the population has a specified chance of being included. If the sample is not randomly selected, as in the InnvaDiab study, we cannot be sure that the phenomena observed in the sample represent those in the population. Thus, there are limitations to the external validity of the findings in this study. However, comparing the participants' demographic and SES profile to what Statistics Norway (SN) and other studies have reported on Pakistani immigrants in Norway, there are several similarities between the women in the study and the Pakistani population in Norway:

The participants

The participants' age ranged from 25 to 62 years. Most of the participants in the study were married and the mean number of children was 3.5. SN has reported the mean number of children among Norwegian-Pakistanis to be 3.4 (4).

According to SN, 17% of Pakistani women in Norway do not have any formal education (52). Among the women in this study, the percentage was lower (about 10%). While SN has estimated only 12% of the Norwegian-Pakistani women to have higher education (University/University College) about 15% (12% in the control and 19.8% in the intervention group) had higher education among the participants in this study. As many as about 45% classified their Norwegian language skills to be poor or very poor, while SN has estimated that about 27% of Pakistani women consider their skills to be in these two categories. Thus, it appears that the profile regarding formal education and Norwegian language skills is somewhat different among the participants than in the general Norwegian-Pakistani population of women.

Mean BMI was high for both the control and intervention group (about 29.5 kg/m^2). In all, about 80% had a BMI $\geq$ 25 kg/m^2, corresponding to overweight. This is similar to the results from the Oslo Immigrant Health Study where they found that South

Asians, especially Pakistanis, have a high prevalence of overweight. 77% of men and 80% of women from Pakistan had a BMI ≥25. In the same study, when using the international cut-off points, they found obesity (BMI ≥30) among Pakistani women to be 39.8% (13), similar to the participants in the InnvaDiab study (40%). This is about four times higher than among Norwegian women (13).

When using the Asian specific BMI cut-off points (35), about 34% were at increased risk (BMI 23.0 – 27.5 kg/m^2) and 61% were at high risk (BMI ≥ 27.5 kg/m^2). Jafar et al (9) sought to map the prevalence of overweight in Pakistan, and applied an Asian-specific BMI definition, however, with different cut-off points than mentioned above. They found a prevalence of 25.0% with a BMI 23.0 – 26.9 kg/m^2 and 10.2% with BMI ≥27 kg/m^2 among this population. Even though not directly comparable, it may illustrate how the presence of overweight and obesity may change in this population when migrating to a Western country.

Randomized sampling

Due to non-random sampling, there is a risk that the external validity of the results in this study is limited. This affects analyses on prevalence. However, the participants were further randomized into control and intervention group. Thus, the analyses comparing the control and intervention group, and the analyses comparing each group at baseline and post test, are less afflicted by this validity problem.

Out of 200 women, 196 were included for the analyses in this master thesis. At baseline, there were few missing responses. However, at post test, the number of non-responses was much higher. Depending on how these missing values are handled, they can influence the results and thus, the conclusions made in the study (6). The purpose of randomization is to avoid selection bias and to generate groups that can be compared. In the InnvaDiab study, all participants randomly assigned to intervention or control, were included as representation for the group they were assigned. This is what the ITT, or an "as randomized" approach, recommends (5;6;85). The ITT approach emphasises greater accountability for all participants in the study, and thus, minimises the influence due to withdrawals, non-compliers, and participants lost to

follow-up. It is the most cautious approach, and therefore, the risk of type 1 errors is low (i.e. believing that there is a difference between the groups when, in fact, there is not) (85).

No consensus exists regarding handling missing responses in ITT analyses (6). Different approaches may be appropriate in different interventions. Practice also differs with regard to false inclusions. Therefore, there is no single definition to ITT. Many studies report that ITT have been used in their trials, but handling of deviations from randomized allocations vary greatly, and methods used to deal with missing data is often inadequate (5). In this master thesis, missing values have not been included in the analyses, thus the results have not been affected by the participants who did not complete the questionnaires. Therefore, the risk of bias has been reduced.

It has been recommended that randomization should be done as late as possible in order to reduce non-compliance to a minimum (6;85). This will minimize the chances of including participants who do not meet the inclusion criteria, and thus, reduce bias. If the excluded participants have a similar response to treatment to that of eligible subjects, the exclusion might reduce the power of the study (85). Thus, how the exclusion of ineligible participants affects the power of the study depends on whether they have a reduced or no effect of the treatment at all. Including subjects who will have a negative effect of the treatment will reduced the power of the study.

In this study, “as treated” analyses were performed on those participants who attended ≥4 out of 6 classes, in order to compare them with ITT.

The questionnaire

Since the methods of the InnvaDiab study were already decided at the commencement of this master study, the choice behind these methods will not be considered. However, challenges and advantages of the tools will be discussed.

The pre-coded questionnaire was written in Norwegian, as Punjabi, which is spoken by most of the women, is not a written language. Urdu on the other hand is the official written language of the region; however, many do not speak it. The questions

were translated by trained interviewers who spoke Punjabi and/or Urdu, in addition to English and Norwegian. Thus, misunderstandings regarding wording and so forth were minimized. This also increased the chances of including all age groups, even the older women whose level of Norwegian is generally lower. As it was the interviewer who administered the questions and recorded the responses of the questionnaire, literacy of the study subjects was not required. Experience from studies of other immigrant groups, led to the choice of the interview method, as the researchers knew of the low literacy among the women. Furthermore, if the participants are not familiar with these types of questionnaires, which was the case for these women, self-administered questionnaires can produce results of low quality. Recalling one's diet can be difficult, but it has been shown that past diets are more accurately recalled if the interview is administered by an interviewer, rather than by the participants themselves (86).

There were only women involved in the interviews and teaching sessions. This helped to reduce any barriers related to talking to staff of the opposite sex, which could have prevented some women from attending the sessions. The participants were explained the importance of reporting as exact as possible, and, in order to relieve pressure, they were told that the results would only be published on group level.

Any misunderstandings of the questions were resolved at the time of the interview. The interviewers were trained in how to ask the questions in order to translate as similar as possible; however, the interviewers' different interpretations may have resulted in different ways of posing the questions. They were also trained in not asking leading questions, which has been shown to reduce the risk of the participants responding according to what they think is expected of them in a health care setting (87). However, as the participant's perceptions of what is expected as an appropriate answer cannot be totally avoided, responses might be biased by this.

The interviews were carried out at the Holmlia Health Care Centre, usually right after anthropometric measurements and OGTT were done. A large dose of glucose may cause nausea and challenge the ability to concentrate, and some of the women were

experiencing high blood sugar levels. This might have made some of the women tired and have affected their answers. Comments such as “too tired to answer”, “does not know” or “does not remember” might illustrate this.

The FFQ

The food frequency approach was used to estimate usual frequency of consumption of different foods. The questions in the FFQ did not cover the whole diet of the women but rather the foods which were in focus in the group sessions. Thus, the FFQ was not intended as a tool to estimate the energy intake. In order to estimate relative nutrient intakes, the FFQ also contained questions regarding portion sizes. This has been shown to be one of the strengths of the FFQ, since individuals can be ranked according to their usual consumption of foods or groups of foods, and nutrient intake, such as fat (88). However, the level of nutrient intakes estimated from the FFQ is not exact, and should only be considered as approximated intakes.

It is important to notice that many details of dietary intake are not measured in the FFQ, and that estimated quantities are not as exact as with recalls (88). This is due to missing foods in the questionnaire, errors in frequency estimation, and errors when estimating usual serving sizes. The food groups used in the FFQ in this study included many foods. They were based on previous studies and validated on different populations. Since different cultures classify foods differently, it may be difficult to understand and report in accordance with the Western way of categorizing. Research has shown that people in general find it difficult to estimate portion sizes of foods (88;89). As serving sizes of foods consumed is difficult to evaluate, it causes problems for dietary history instruments. However, the inaccuracies regarding estimation of usual serving size in FFQ may be even greater (88). Because frequency is believed to be a greater contributor than serving size to the variance of intake of most types of foods, FFQs often do not add portion sizes, only frequencies. In the current study, portions sizes were described to the participants for some of the questions, such as for fruits and vegetables. It may be easier to report portion sizes of foods used on regular basis and that have a defined unit, such as a slice of bread, a piece of fruit, or beverages in a can. Thus, to improve the reporting of portion sizes,

the InnvaDiab provided photos of certain types of foods, so that the respondents could easily point out the size of the portion by looking at the photos. The pamphlet "Bildehefte med porsjonsstørrelser" was developed by the Norwegian Food Safety Authority, the Norwegian Directorate of Health, and Department of Nutrition at the University of Oslo. In addition, selected pictures from "Matmalen", developed by the Swedish National Food Administration, were used. Household measures such as *katori* and *small bowl* were also used to describe portion sizes to the participants. This helps to increase the validity of the responses. However, it is not certain if the participants included food items such as vegetables and beans used in curry/salen and other mixed dishes, when reporting intake of these.

Thompson et al (88) have proposed that in order to examining the concordance of FFQs and usual diet, one should use multiple food recalls over a period of time as an indicator of the usual diet. This was done in the InnvaDiab study (the use of the 48 hour recalls) but not in this thesis. However, the strength of using the FFQ is that it can easily be adapted for studies of the long-term dietary intake of multiethnic populations since specific foods can be included in the list. The FFQ used in this study was made more sensitive to the eating patterns of the women studied, as Pakistani food items and dishes were included.

There are some challenges and draw backs to the FFQ. It puts a great burden on the respondent due to efforts to remember his/her intake and that it is usually lengthy (86;89). The participants' memory might also cause inaccuracies in reported intakes. Over - and underreporting are common when asking people about their intake of foods (87;90), and has been associated with FFQs. Underreporting has been found to be increasing with age and to be more frequent in women than in men (90). Furthermore, high and low educational level has been found to be related to underreporting, but not consistently. It seems that underreporting is related to specific food items, such as foods rich in fat and sugar, while intakes of vegetables, fruits and fish are not (90). This proves that memory is selective, and that people tend to underreport foods that are perceived as unhealthy, while foods that are healthy are over reported. The extent of underreporting in older South Asian women have been

found not to be too severe, as they are more sedentary and therefore have lower energy expenditure than the general population (87). For South Asians in general however, little is know about over- and underreporting.

FFQs are known to over-estimate true intake of certain nutrients (87;91). This is probably due to long lists of foods and difficulties in accurately estimating frequency of food consumption and portion sizes. However, validation studies of energy intake from reported intakes have found that FFQs tend to under estimate true energy intake (87).

The stages of change

Some questions in the questionnaire were related to the intention to make changes in dietary behaviour, by using the Stages of Change construct from the TTM. Individuals progress through 5 stages by implementing cognitive, experimental and behavioural activities. The changes in decision making, i.e. the balance of the pros and cons of changing, and self-efficacy (the confidence in performing specific tasks that lead to change) are thought to occur in the process (92).

The TTM of behavioural change was originally developed to describe the process of behaviour change for addictive behaviour such as smoking or alcohol abuse. It has been argued that the TTM's stages with regard to dietary behaviour may be very problematic due to the difference in nature between such behaviours and the addictive behaviour it was developed for (93). The goal with addictive behaviours is to abstain from the behaviour completely, while for dietary behaviours, the goal is to eat healthier. This is more of a general behaviour change and is interpreted differently by different people. However, with regard to dietary behaviour, the stages of change construct has been successfully used to measure intentions for dietary change (74;75;94;95).

Little is known about how the stages of change construct is perceived by South Asians. It has been proposed that models that have been developed for non-Asian populations therefore may need to be modified when used in studies of certain

minority groups (3). Thus, this study sought to understand to what degree changes in intentions to change resulted in changes in intake of the corresponding foods.

Progress

What is it that moves people from one stage to the next and even make them continue to progress after intervention? The extent of successful action taken during and after an intervention is directly related to the stage people are in at baseline (70). This so-called stage effect has been found when dealing with many problems and populations. It is important to identify individuals according to the stage they are in. If the stage is identified, the education given can be based on that stage and increase the likelihood for movement to the next stage, and thus, increase the chances of giving people the right approach to succeed.

The stages of change construct has also been used to detect cognitive changes regarding intentions to change dietary behaviour (74;75). In this master thesis it was used to study what stage the participants were in before the intervention, in order to detect their intentions to change dietary habits. Furthermore, it was used to study the changes in stage classification after the intervention, in order to establish any differences between the control and intervention group from baseline to post test. The relationship between stage classification and dietary intake was also studied.

Many research studies now include stages of change as a part of dietary assessment (73). Most of these are based on the TTM in the design. Mostly, strategies categorize people into stages of change based on three factors: self-rated diet, previous attempts to change diet, and intention to change diet. Kristal et al (73) suggest that the stages of dietary change construct is most useful when the target behaviour is defined using self-rated diet. This will tell us less about what people are eating and more about what they are thinking. Thus, instead of using stages of change as a measure of dietary behaviour, it will be a tool to measure cognitive and behavioural engagement with the dietary change process, as it measures what people think about how they are eating and their interest in changing.

Kristal et al (73) also proposed that an effective dietary intervention should accelerate movement from pre action stages into the action and maintenance stages. A few studies have looked at how dietary interventions affect transition through stages of change. In these studies, the proportions of participants in action or maintenance were highest for those who were in preparation at baseline, intermediate for those who were in contemplation at baseline, and lowest for those who were in pre-contemplation at baseline (73). Thus, it requires extra time to move from pre-contemplation and contemplation into action or maintenance.

4.2 Discussion of results

4.2.1 Perceptions of healthy eating

Understanding "healthy" and "unhealthy" eating

When considering health-related dietary change, the interpretations given to "healthy" and "unhealthy" eating are central. Generally, guidelines to healthy eating do not tend to target specific high risk individuals, but are rather intended for the whole population (61). The understanding is that it is the lack of knowledge or awareness that prevents people from eating healthily. However, some argue that this is not always the case; even though people are aware of what is recommended, there are a number of practical barriers which challenge people to put these ideas into practice. Thus, one could say that knowledge alone is not sufficient to affect food choices *unless* it can overcome psychological, behavioural and environmental barriers (61;76). Such barriers are for instance the food preferences of men and children, restrictions due to income, and the confusing and conflicting dietary advice from experts. In the InnvaDiab project, the preferences of others (children and husband) were often mentioned as constrains for the women to eat more healthily (96).

The perceptions of healthy eating have been found to be quite homogeneous across different cultures and countries. In a review by Paquette et al (63) perceptions of healthy eating were usually based on food choice and was described in terms of specific foods or food groups, such as "fruits and vegetables", "pasta" and "pulses".

Fruit and vegetable intake has consistently been mentioned as the most important parts of healthy eating. In the present study, this was the case for vegetables. Very few women mentioned fruits. This might be due to the recommendations regarding DM2 and fruits, which are limited to 2 portions per day. More general descriptions such as “balanced diet”, “moderation” and “variation” have also been mentioned as important parts of a healthy lifestyle. This is in accordance to the message from the Norwegian Directorate of Health (56).

When asked what they perceived as unhealthy eating, the majority of responses concerned *sugar, oil* and *other fats*. Other factors such as *snacking* and *tasty foods* were also mentioned. This is similar to other studies, where “junk food”, “sweets” and “sweet foods”, “take away foods” and “fatty foods” were described as unhealthy (63). There might be several explanations for the emphasis on foods and food groups when talking about healthy eating, and on nutrients when talking about unhealthy eating. The recommendations for a healthy lifestyle focus on increased intake of fruits, vegetables, and fish, but to limit the intake of fat and sugar (56). Thus, the women’s responses reflect these recommendations. It should be noted that the word “healthy” does not exist in Punjabi or Urdu. Thus, the questions related to healthy and unhealthy were translated by the interviews to: “What foods are good for your body?” versus “What do you think you should not eat too much of, what is not good for your body?” These wordings might have influenced what the women answered, as the latter question could have produced a broader array of definitions, such as *fat* and *sugar* instead of *sweet bakery goods.*

After the intervention, there was an increase in the proportions in the intervention group that mentioned *sugar* and *white flour*, as well as *polished rice* (the latter not significantly increased). These were foods that had been focused on in the teaching sessions. The difference between the groups was especially pronounced and significant regarding *white flour*. For the control group, the responses had increased for several of the items, however, not to the same extent as for the intervention group.

Regarding what they perceived as healthy eating, there was a significant reduction in how many in the intervention group who mentioned *meat* at post test. This indicates that fewer in this group regarded meat as part of a healthy diet. More women in the intervention group mentioned *fish* after the intervention, and less in the control group. There was a decreased proportion of those mentioning unhealthy foods, such as *oil/fat* and *sugar*, which is recommended to be limited in a healthy diet (56). It has been predicted that the association with nutrition knowledge is stronger for fruits and vegetables than for fat (97). In this study, there was a higher percentage who classified vegetables as healthy compared to oil/fat as unhealthy, which supports that finding.

It should be noted that this population generally perceive food items based on their nourishing power ("strength foods"). Sugar, ghee, lamb and beef are considered "strong" foods (98). Thus, it seems that the intervention has influenced and changed their perceptions of what is "healthy" and "unhealthy" as many has classified sugar and fat as unhealthy at post test. Also, intake of these foods have been found to increase after immigrating to Western societies (58). Thus, one could say that the intervention has affected the negative effects of the acculturation process.

Health consciousness and to understand dietary advice and the role of food in health and fitness, is important with regard to compliance (98). The intervention group's perceptions and changes in perceptions regarding healthy and unhealthy foods can be related to the topics of the teaching lessons and a generally increased awareness of healthy eating. An emphasis was put to communicate the effect of certain types of foods that were known to be consumed frequently in this population, in relation to the risk of DM2. These included foods rich in sugar and fat, fat in general, white flour, and fruits and vegetables. However, it was surprising that so few in the intervention group mentioned *too much oil* as unhealthy in the post test (55.1% versus 64.4% in the control group). What was also revealed in these results was that the control group have changed their perceptions of healthy and unhealthy eating as well, however, not to the same extent as the intervention group.

Knowledge of foods and other factors with regard to DM2

Critics claim that knowledge about nutrition and health is not relevant to food choice, believing that changing knowledge will not have an effect on food intake (97). However, others believe that the importance of knowledge as a determinant to food choice is sometimes underestimated. If unreliable tools are used to measure nutrition knowledge, the power of the study to detect relationships with other variables is reduced. Usually, studies look at significant effects of an intervention however; the small or modest effects may not be significant but are also important to study. These non-significant effects may add up to a significant impact in terms of public health, and in a population-based perspective (97).

The participants were asked to mention any factors that could put them at increased risk for developing DM2. The mean number of factors mentioned had increased in both groups at post test, indicating an increased knowledge. The factor mentioned by most at both tests, was *too much sugar*. Many Pakistanis relate DM2 directly to the amount of sugar eaten. In Punjabi, "sugar" or "sugar di bimari" (*the illness of sugar)* are commonly used for diabetes (99). After the intervention, the intervention group had increased proportions for all categories, especially *low physical activity, overweight, family with DM2* and *too much fat*. It has been reported that South Asians often associate DM2 with obesity (100), which is in agreement to what was found in the present study.

Both groups increased the response regarding *low physical activity* after the intervention. In the intervention group this is most likely due to focus on physical activity in the intervention and the organized walks. Some participants in the control group might have been aware that the intervention group received trainers and attended organized walking groups, and thus, realized its importance. Exercise with regard to health has been found to have little cultural meaning to South Asians (101), and there has been reports that they perceive physical activity to exacerbate illness or physical weakness. In one study, less than 25% named physical activity as a preventive measure for DM2 (99). This is similar to the baseline measures, however not for the results from the post test, where 53.5% and 65.4% in the control and

intervention group respectively mentioned *low physical activity* as a risk factor of DM2.

Physical activity is important in preventing weight gain. Among South Asians in Norway, the level of physical activity is low, which might have to do with the cold climate and different norms about leisure-time physical activity (30). A review showed that South Asians are less physically active compared to other ethnic groups. Sedentary South Asians had higher BMI on average, as well as higher triglycerol levels, and blood pressure, and thus, high risk for developing hyperglycaemia in the future (26). For the participants in the InnvaDiab, mean time spent physically active at baseline was 27 and 16 minutes per day in the control and intervention group respectively. The recommendation is at least 30 minutes of physical activity per day (56;102). The low level of activity in the intervention group might be due to seasonal variation. Some women reported a lower level of physical activity in the winter due to the cold weather and the reduced amount of daylight.

Knowledge of DM2 and CHD in this group has been found to be very low, even among people who have these conditions. It was found that 1/3 of the respondents (South Asians living in the UK) did not understand what was meant by DM2 and CHD (99). The study found that 22% of the respondents could not mention one single risk factor for DM2, and 20% could not give a preventive measure. In the current study, the proportion who could not mention one single risk factor for DM2 had reduced from around 10% in both the control and intervention group at baseline to about 4% in the control and 2.5% the intervention group at post test. This indicates that knowledge in this group can be increased by education. One should also take into account how illiteracy and low level of education affect the understanding of health information communicated.

4.2.2 Intention to change and change in actual intake at baseline and post test

In order to achieve dietary change, long established patterns of eating habits and behaviour needs to be changed or given up. Support from people around is crucial in

order to change eating behaviour. Studies have found that dietary changes are more likely to happen in nuclear families compared to larger families (98). Pakistani families are generally bigger than Western families, and many include the extended family in the household as well. In order to change dietary behaviour, information and knowledge of nutrition and lifestyle is crucial. It is an essential step in behaviour change that people are aware of key health messages (103).

Stage classification often varies according to different aspects of a person's dietary intake and dietary habits (98). Usually, the stages of change construct is used to understand patient-specific stages of change in order to use the most appropriate strategy to diet interventions. However, it has also been recommended for studying intentional changes in interventions (74;75;95). In the InnvaDiab study, the stages were used to identify in what stage the participants were at baseline compared to post test to see whether changes in intentions to change dietary habits had occurred.

Fat reduction and type of fat

It is now generally acknowledged that a diet high in fat and low in fibre, fruits and vegetables contribute to increased risk of chronic diseases, particularly DM2 and CVD and certain types of cancers. The recommendation for fat intake is ≤ 30% of total energy intake (56). In Pakistan, butter, ghee, oil and meat are luxury items due to the cost of these (58). However, it has been shown that the intake of ghee and meat increases after arrival in Norway (25).

Assessing stage regarding dietary fat reduction is challenging, as the validity of self-reported stage of fat reduction depends on people's knowledge and awareness of whether they are eating a high fat diet and if they are making changes that can actually reduce their fat intake (104). Compared to cigarette smoking, where the goal is abstinence from the behaviour, the goal with regard to fat intake involves modification, not cessation, of intake. Reducing dietary fat involves a complex set of behaviours such as modification of shopping patterns, reading food labels, food preparation techniques, and food intake. Thus, people often find it more challenging to reduce fat intake compared to increasing fruit and vegetable intake (105).

Regarding intentions to reduce fat intake, the results from this study showed that there was a significant difference between the control and intervention groups with regard to intentions to change at post test. There was a significant higher proportion in the action stages at post test compared to baseline in the intervention group, which was not found in the control group. This indicates that the intervention group had started to change with regard to reducing fat. There was a decreased proportion in the maintenance stage at post test. This indicates that some of those participants who considered themselves to be in the maintenance stage at baseline, now realised that they had just recently started to make the necessary changes. This might be related to increased awareness of their diet and actual intake as a result of the intervention. Focusing on fat, types of fat, and its detrimental effect on health during the group teachings, might have made these women more conscious of what quantities and types of fat they use.

Regarding changes in what type of fat they use and the intention to change, there was a significant difference between the groups with regard to stages of change at post test. There was an increase in the proportions of the intervention group who had moved to the action stage at post test. The percentage of participants, who considered themselves to be in the maintenance stage, was reduced from baseline to post test, indicating an increased awareness of classification in terms of dietary intake and stages of change. There was a significantly higher proportion of participants in the intervention group, who were in the action stages at post test compared to baseline, indicating a positive effect of the intervention. This was not found in the control group.

Many classified fat and/or oil as unhealthy. Regarding the purchasing of oil, both the control and the intervention group reported to buy significantly less oil at post test than at baseline. In addition, while the control group reported an increased amount of oil used in salen/curry, the intervention group reported a reduced amount at post test. Even though not significant, this together with the reduced amount of oil purchased, is in accordance with the significant increased proportion of the intervention group in

the action stages regarding intention to change type and reduce the amount of fat that they use.

It has been reported that people are able to accurately report whether they are trying to limit the fat intake. Those who have tried to and believe that they have succeeded in reducing dietary fat, are indeed eating diets with lower fat (104). In addition, those who have not tried and have no intention of trying to reduce fat, report the largest intake of dietary fat. However, little is known about whether intentions of South Asian women are in accordance with their actual intake. For those who reported to have moved from the pre action stages into the action stages, the mean amount of oil purchased per month had decreased by 1294 grams, compared to 770 grams for those who had not moved at all or had moved from the action stages to the pre action stages. This was not a significant difference, but more a suggestion of a change. This finding is supported by other studies (74;95;106), showing that progression is associated with dietary fat reduction. It is also in agreement with studies which have found that measurable changes only occur when the individual is actively trying to make behaviour change, i.e. when he/she is in the action stages (104). However, it should be noted that some of the participants who had not moved with regard to the pre action or action stages, were in the action stages at both baseline and post test. This has probably caused the changes in the amount of oil purchased at post test compared to baseline in the group who had regressed from the action stages to the pre action stages, or had not moved at all.

Some of the intake data also suggest reduction in fat intake. Intake of whole fat milk and yoghurt was reduced in both groups, but only significantly in the intervention group. The reported intake of fast food and deep fried food had decreased for both groups from baseline to post test. The majority of the respondents reported an intake of 1-3 portions per month. The mean intake of fast food and deep fried foods was about 1 portion of each per week, which does not contribute to a high energy and fat intake. However, oil contributes a lot to the total energy and fat intake. The intervention group reported to buy about 1740 grams less of oil per month at post test

than baseline, which adds up to 15, 600 kcal for the family as a whole, which also indicates that the consumption has decreased.

When studying what kind of fat the Pakistani women usually use at home, and what types of fats are used for different purposes (questions 17 and 18, see Appendix 1), the findings mentioned above were further confirmed; over 90% used oil or margarine in food preparation. At post test this had increased even further, to about 96% for both groups. Ghee was reported to be used by 1-3% in the traditional dishes.

Sugar and sugar rich foods

Intake of traditional sweets and sugar has been shown to increase among Pakistanis after migration to Western societies (2;26;29;55;60). High intakes of these foods can lead to weight gain and subsequently the development of the MS and/or DM2. Sugar was perceived as unhealthy by the majority of the women in this study.

Post test data showed that the majority of the intervention group were now in the action stage with regard to sugar, and that there was a significant difference between the groups and stages at post test. In addition, for the intervention group, the difference in proportions in the action stages from baseline to post test was significant, as many participants had moved from the pre action stages into the action stages.

Regarding intake of soft drinks with sugar, the control group reported a higher intake per week at post test than at baseline. In the intervention group, however, the intake of soft drinks was significantly reduced, with a mean at post test that was half of that at baseline. The difference between the control and intervention group was also significant. Also for fruit drinks with sugar, the intake had increased in the control group, while it was significantly reduced in the intervention group. This change was significantly different between the control and intervention group. The mean intake of soft drinks and fruit drinks with sugar added was 7.3 dl per week at baseline and only 3.3 dl at post test in the intervention group, which is quite low compared to the average intake of sugar rich drinks in the Norwegian population (56). In 2004 the mean intake of soda with sugar added was 79 litres per year per person (about 1.5

litres per week) (107). As mentioned earlier, underreporting of foods that are unhealthy is quite common (90). The intervention group's perceptions of sugar are quite clear: it does not belong in a healthy diet. It could be that they underreport their intake in order to report what is expected of them.

Desserts and sweets are important parts of foods consumed in connection to celebrations in the Pakistani culture. At post test, the proportion of participants in the intervention group who reported a daily intake, had decreased from 9% to less than 4%, while in the control, there was an increase. Even though this change was not significant, it adds up to the picture depicted above.

In order to study how the intention to reduce sugar was connected to their actual intake, analysis was done on intake of sweet bakery goods and stages of change. Analyses showed that there was a significant difference between intake of bakery goods between those in the pre action stages and the action stages in both control group and intervention group at baseline and post test. Further analyses showed that those who had moved from the pre action to the action stages, reported a decreased intake of sweet bakery goods per week, compared to the rest of the participants, who had increased. Even though this was not a significant decrease, the movement from pre action to action was in agreement to their intake.

Fruits and vegetables

Fruits and vegetables are recommended as part of a healthy diet, and are recognized by health authorities as foods that provide important health benefits, including decreased risk for developing chronic diseases such as DM2 (45). However, despite the known benefits of having a high intake of fruits and vegetables, the intake is generally low on population level (89). According to Norkost 1997, the mean intakes of fruits and vegetables among women in the age group 20 - 49 years in Norway, are 214 grams and 140 grams respectively (108), while the recommended intakes are 300 grams of fruits and 450 grams of vegetables, or 5 portions per day (56). These numbers have most likely increased the last ten years but are still too low (109). Traditionally, the Pakistani diet has been high in fruits and vegetables, however,

unfortunately, the intake often decreases after migrating to Western societies (3;20;25;26).

Vegetables were mentioned by the majority as part of a healthy diet, while fruits were hardly mentioned at all. Data suggest that the intention to eat more vegetables had changed after the intervention since a higher percentage of the intervention group was in the action stage. The stages of change model has been found to be applicable to consumption of fruits and vegetables in other population groups (105).

There was a significant difference between the proportions of participants in the action stages from baseline to post test in the intervention group. Results also showed that there was a significant difference between the groups regarding intentions to increase intake of vegetables at post test. The highest frequency of the intervention group was in the action stage, while the highest frequency in the control group reported to be in the maintenance stage, similar to baseline. In the intervention group, some had regressed from the maintenance stage to the preparation and action stages. This is probably due to an increased awareness of their low dietary intake. It is quite common that people misperceive their diet to be healthier than it is. The intervention seems to have affected their perceptions and made them realize that they were not in the maintenance stage. The data showed that those who had moved from the pre action to the action stages had a greater increase in vegetables than the rest of the group, though not significant.

There were hardly any changes from baseline to post test regarding intention to increase fruit intake. This might be due to the recommendations regarding DM2 and fruit intake, where fruit intake is generally limited to 2 portions per day. When comparing the group who had moved from the pre action to the action stages, to the rest of the group, their reported intake of fruits had increased. The group, who had not moved or had regressed back to the pre action stages, had hardly changed at all from baseline to post test. The difference between the groups was significant, indicating that those who had moved into the action stages had indeed increased their fruit intake.

Regarding fruit juice consumption, there had been an increase in the intervention group, though not significant. In the control group, the consumption had decreased. At post test, the amount of fruit juice consumed equalled about 4 portions of fruits per week in the intervention group, compared to less than 3 in the control group. It has been reported that informants find it difficult to distinguish fruit juices from fruit drinks (110), leading to inconsistent answers. This might have been the case for these women as well; however, it is obvious that fruit juice contribute a great deal to the total intake of fruits. Other studies have reported that differences in total vegetable and fruit consumption from baseline to post test was due to a higher consumption of fruits (not including fruit juice) (103). This is relevant to the results as there was a higher intake of fruits than vegetables among the women in this study.

Fruits, fruit juice and vegetables

The total intake of fruits, vegetables and fruit juice had increased significantly in the intervention group. Thus, their intake is in agreement to their intentions and perceptions. The intake of each of these had increased respectively from baseline to post test, however, not significantly. It has been found that reporting portion sizes for both fruits and vegetables and the amount usually eaten, is challenging (89;92;111). Under reporting of vegetables is likely to occur in this group, as they may not have accounted for the vegetables they use in salen/curries. It has also been suggested that the public is often unaware of the actual recommendations for the quantity of vegetables (111). The women's low educational level might also have affected their intake, as low educational level has been associated with a lower intake of fruits and vegetables (112).

The total amount of fruits and vegetables in grams per day (juice included) at post test added up to about 2.5 portions per day of fruits and vegetables in the intervention group, and just above 2 portions per day in the control group. This is only half or less than the Norwegian recommendations, which is 5 portions per day (56). It has been reported that Pakistani women living in Pakistan, have a mean intake of about 350 g per day of fruits and vegetables (113), not including fruit juice. This indicates that the intake of fruits, fruit juice and vegetables is probably lower after arrival in Norway. It

has been reported that the vegetable intake is reduced after arrival in Norway (20). This has also been reported by the women in this study, and has been explained by the higher cost, the lower quality and freshness, and the decreased availability (96).

It should be noted that when converting the categories in the questionnaire into grams, categories 1 (≥4 portions/day) and 6 (<1 portion/week) (see questions 7 and 10, Appendix 1) did not provide an exact estimate as a person might be eating much more than 4 portions per day or much less than 1 portion per week. However, this has been ignored as a very low percentage had an intake above 4 portions or more per day (2 and 3% for the intervention group at baseline and post test respectively, while it was not reported in the control group). On the other hand, at baseline 10% and 16% of the control group reported an intake of 1 portion or less per week of vegetables and fruits respectively. This challenges the estimated intakes. However, this was found to be the most appropriate way to calculate the total intake of fruits and vegetables. Furthermore, it is likely that the participants have under reported their intake of fruits and vegetables.

Legumes

Results showed that there was a significant difference between the control and intervention group with regard to stages of change for legumes at post test. Many of the participants in the control group considered themselves to be in the maintenance stage at baseline and post test, while there had been a shift in the intervention group from the maintenance stage back to action stage. Intake of legumes is an aspect of a healthy diet that was emphasised in the teaching sessions in the InnvaDiab study, and also an important part of a healthy diet with regard to DM2. Legumes have traditionally been an important part in the Pakistani diet, however, studies of changes in intake after migration have found a reduced intake of legumes in immigrants (3;20;25;26). Results for the reported consumption of legumes (dl/week), showed that the mean intake per week had increased in both groups, although only minimally. For those who had moved from the pre action into the action stages, their reported intake had increased from baseline to post test. The increase was small, but significantly

different from the group who had not moved or had regressed back to the pre action stages.

White flour

The data also indicate that the intervention had an effect on intentions regarding the use of white flour. There was a change in distribution towards the action stage in the intervention group. In the intervention group the proportions of participants in the action stages at post test was significantly higher than at baseline, which was not seen in the control group. Again, there was a shift from the maintenance stage to the preparation and action stages, in the intervention group. This was not observed in the control group. The regression from the maintenance stage may be due to an increased awareness of how much white flour they are consuming and the need to reduce their intake. In the intervention group, there was a significant higher proportion in the action stages at post test compared to baseline.

In order to increase fibre intake, nutritional goal settings has been found to be essential (114) as it increases self-efficacy. It has been reported that respondents are usually found in the pre-contemplation and contemplation stages when it comes to increasing intake of fibre compared to reducing fat intake. Regarding intention to reduce fat, a higher proportion is usually found in the action stage than it is for increasing fibre (74;114). In the current analyses, the highest frequency regarding intentions to reduce intake of white flour was found in the pre-contemplation stage at baseline for the intervention group. This is in accordance to what has been reported for intentions to increase fibre intake. However, at post test, the percentage of respondents in the action stage for intentions to reduce fat and reduce white flour were almost the same in the intervention group. This indicates that the intervention has had an impact on the intervention group's intentions to reduce their intake of white flour.

Regarding the perceptions of white flour, many in the intervention group classified white flour as unhealthy. The intake of white bread had decreased in the intervention group, while the control group reported an increased intake. There was no significant

difference between baseline and post test or between the control and intervention group at post test. Furthermore, those who reported to have moved into the action stages at post test had increased their intake of white bread, however, not significantly. Thus, how the participants classify themselves with regard to stages of change is not in accordance to the changes they have done regarding white bread.

Kristal et al (73) have studied how diets differ between people in different stages of change. All studies reviewed found significant differences in diets across stages: the differences were often modest between the pre action stages and larger between pre action and action, and between action and maintenance. In this study, significant differences in dietary intake with regard to those who had moved into the action stages compared to the rest of the group, were found for the intake of fruits and legumes, which is in agreement to the findings in those studies.

Overall, studies suggest that adopting a healthful diet is a staged process. Thus, moving from one stage to the next can be used as an indicator of the effectiveness of the intervention (74;75). In findings from the current study, the intervention group's significant progress from the pre action to the action stages (as seen for reduction of fat, and change type of fat, reduction of sugar and white flour) can be used as a measure of the intervention

Other changes in intake from baseline to post test

It has been reported that immigrants have a low intake of vitamin D (115;116), and that the intake of omega 3 is lower than RDA in Asian Indians (117). Studies suggest that there is a link between intake of omega 3 and the development of CVD and MS (118;119). In the InnvaDiab study, subjects were asked about their intake of cod liver oil and intake of vitamin supplements. For both the control and intervention group, the proportion of participant who took cod liver oil daily had increased at post test; however, the increase was small and insignificant. The responses were probably not affected by whether the participants completed the FFQ in the summer or winter, and thus induce a bias, since there were options in the questionnaires for "yes, only in the winter" and "sometimes".

1/3 and ¼ in the control and intervention group respectively, reported a daily intake of vitamin supplementation at baseline. At post test, the proportions of participants in the control group who took supplementation daily had increased, but it had decreased in the intervention group. When aggregating to a dichotomous variable (daily/not daily), a significant difference between group and intake was observed at post test. The decrease in proportions in the intervention group could be explained by a greater awareness and understanding of their dietary intake. The reasons why people choose to take supplements might be multiple. However, perceiving that their diet does not meet the recommendations for vitamin and minerals, have been reported as one reason for supplementation (120). In the current study, increased knowledge and awareness may have resulted in an impression that their diet was sufficient if they eat a balanced and varied diet.

4.2.3 Reflections of the TTM

When studying the results from the stages of change questions, the trend at baseline was that many participants either perceived themselves as maintainers or in the early pre action stages (pre-contemplation and contemplation). This was especially the case for intention to change type of fat and to reduce white flour. It has been argued that people would be more likely to be situated in the pre-contemplation and maintenance stages as these are longer lasting steady states, and not in the shorter-lived, more transient stages, such as preparation and action (93). After the intervention however, many in the intervention group had regressed from the maintenance to the earlier stages. As mentioned before, this might be due to an increased awareness and understanding of their dietary intake. While they perceived their intake as being high in legumes and vegetables at baseline, they now realized that they ought to increase it further, thus categorizing them into the preparation or action stages.

The changes in the intervention group with regard to stages of change are very obvious compared to the control group. The intervention group has most likely become more aware of their dietary intake and many have a desire to change because they now understand the importance of a healthy diet in disease prevention. Many of

the women expressed gratitude towards the researchers for listening to them and trying to communicate important health messages. After the teaching sessions were over, the women may not have wanted to disappoint the researchers. Thus, there might be a risk of "over reporting" what stage they were in at post test.

One of the criticized aspects of the TTM is accurate staging (92). Dietary - and dietary behavioural change is a complex process. Not only do people move from one stage to the next and back, but people may also be categorized into more than one stage at one point. For instance, if someone has already made dietary changes and maintained those for more than 6 months (maintainers) he/she may also realize that there are more changes necessary to be made in the future (contemplators). Furthermore, people in the action stage with regard to low-fat diet and fruit and vegetable intake, often have reported that they had done those changes less than 6 months ago, however regarding healthy eating, most reported that they had been making changes for more than 6 months, which would classify them as "pseudo maintainers" (93). Furthermore, a person who says he has decreased his fat intake might not necessarily eat a low-fat diet. It has been reported that in a population that perceived they were reducing dietary fat intake, only 1/3 met the action criterion of fat intake of $\leq 30\%$ of total energy (72). It has also been argued that people in the action and maintenance stages might have maintained their current dietary behaviour for a range of different periods of time, and that the 6 month cut-off point is not evident in order to distinguish between the two. Thus, time-dependent methods to categorize stage may not be appropriate for use with complex and varied health behaviours, such as dietary change.

It has been suggested that a more appropriate method could be to categorize people into stages of dietary change by focusing on the qualitative differences between them, rather than the time spent on making the change (93). One way to make the model more appropriate for complex behavioural change is to make the behaviour more specific (93). By changing "increase vegetables and fruits" to "eat five fruit and vegetable portions per day" people would be less likely to misperceive their diet and fewer people would be classified to the action and more to preparation (93;105). An

interesting aspect regarding questions related to dietary change is the wording. Asking someone “are you planning to….” compared to “have you decided to…. “ will probably change the number of people categorized to the action and pre action stages (105). However, in the InnvaDiab, the participants were asked if they had changed the specific behaviours, and thus, the risk of categorizing the participants in the wrong stage was decreased.

4.3 Intention-to-treat and treatment received analysis

At the end of an intervention, there may be four groups of participants. 1) Those randomized into control group but attended the teaching lessons, 2) those randomized into control group who stayed in the control group, 3) those allocated to intervention group and attended the teaching lessons, and 4) those allocated to intervention who did not attend the teachings. ITT analysis also referred to as “Pragmatic Trial” or “Programme Effectiveness Analysis”, compares 1 and 2 with 3 and 4. Efficacy Analysis, also called “Explanatory Trial” compares 2 with 3, ignoring 1 and 4. Treatment Received Analysis (“As treated”) compares 1 and 3 with 2 and 4 (6). The results discussed previously in this chapter, have been based on results from the comparison of 1 and 2 with 3 and 4, or ITT.

In the analysis done in this master thesis, ITT analyses were compared to analyses carried out with the group of women who had attended ≥ 4 classes, which would, but not completely, correspond to the “as treated” analysis, since the women who had received up to 3 teachings were not included. This was decided after discussing the issue among team members. If a participant attended only 3 classes, there could be a risk of missing out on important subjects with regard to the teachings. 4 classes however, would increase the chances of exposing the women for most of the information and thus, increasing their knowledge. Furthermore, one participant allocated to the control group attended 5 teaching lessons and has been included in the “as treated” group. The goal for these analyses in the master thesis was to see if there were any differences between the two groups compared to when all participants assigned to the intervention, was included.

About 60% of the intervention group had attended ≥ 4 classes, meaning that the results discussed so far were based on an intervention group where 40% of the women had attended only 3 classes or less. 9 women had not attended any classes at all. The average attendance rate was 4 classes.

Results can be drastically modified and even wrong if a randomized controlled trial is analyzed on anything other than ITT. The effectiveness of the intervention may be overestimated if an ITT analysis is not done (5). Thus, great care must be taken regarding selection of participants. In any health intervention, it is essential to remember those participants or clients who would not or could not complete the planned intervention, and include them appropriately in the analysis (6). Comparing the results for the ITT with those who attended 4 or more classes, there were a few minor changes in the outcome. Significance was found in the latter group with regard to intake of soft drinks and fruit drinks with sugar added, as well as for the intake of fruits, vegetables and fruit juice (grams per day). The changes in intake of lean fish and whole fat milk and yoghurt were not significant for the "as treated" group, but were in the ITT group. However, fish in total were significantly higher in the group who had attended 4 or more classes, while there was no significant increase in the original analysis. Thus, if the results had been based only on those who attended a certain amount of classes, the conclusions would have changed somewhat. In the TRA, there were only small changes in the control group due to the participant who had attended the teaching sessions.

Care must always be taken to minimise missing responses and to follow up those who for some reason withdraw from treatment. In the InnvaDiab, missing responses were reduced by calling and reminding the participants of their appointments. Furthermore, subjects in the intervention group were reminded of when the teaching lessons were scheduled, and if they were not able to make it, they were offered to come in on another day.

The exclusion of participants who do not receive the intervention from the ITT analysis is quite common, and in some situations this is unlikely to lead to bias (5).

This could be the case if the treatment is surgery. However, in the InnvaDiab project, the exclusion of participants who did not show up for the teaching lessons, could lead to bias, since there might have been a leaking of information from those who attended the classes to those who did not, whether they were in the control group or the intervention group. Thus, if these subjects in the intervention group were excluded, the changes they might have made would not be detected and shown in the results. On the other hand, including participants who have attended few or no teaching sessions, may influence the results in a negative direction, as they may not have made changes to a great extent. In the ITT approach, complete case analysis violates the principle of this approach and may lead to bias. Large numbers of missing data makes it difficult to draw valid conclusions (5).

Certain recommendations to perform ITT have been proposed (5): Regarding study design, researchers should decide whether the aim is pragmatic (comparing all participants according to the group they were allocated, whether they received the intervention or not) or explanatory (comparing those in the control group who stayed in the control group, with those in the intervention group who received the intervention). In pragmatic trials, such as the InnvaDiab project, ITT analysis is crucial. Any inclusion criteria which when violated would be excluded from ITT analysis should be decided in advance. Great efforts should be made in order to minimize missing responses, and subjects who withdraw or do not receive the intervention, should be closely followed up. Furthermore, potential effects of the missing values ought to be investigated.

It should, however, be noted that there are critical aspects to the use of the ITT approach. Some critics claim that it is too cautious and more susceptible to type II errors (i.e. believing that the groups do not differ, when in fact they do) (85). It has been argued that the analysis is less likely to show a positive effect of the treatment and that an efficacy approach rather than a pragmatic approach is more important.

This study has shown that the stages of change can be used in a group of Norwegian-Pakistani women to describe intentions to change dietary habits. In addition, the study

has shown that culturally adapted health education of women in this group, changes both perceptions and knowledge of nutrition and health. This has in turn changed the intervention group's intentions to change dietary habits, and has affected intake of several types of foods. These changes are important with regard to reducing the risk of DM2 and MS.

There are some limitations to this study. As the FFQ does not cover the whole diet, no conclusions can be drawn with regard to changes in overall diet of the participants. As seen in several of these analyses, the control group had also made dietary changes. These changes might be self-initiated changes and can be as large as the effects attributed to the intervention (75). The leaking of information from the intervention group may have had a great impact on the changes seen in the control group. Furthermore, by knowing that they are part of a research study, the control group might have become more aware of their lifestyle and dietary intake. Another limitation to the study is that all outliers were kept, which might have affected the results due to the variations in some of the variables. However, all outliers were checked.

4.4 Conclusion

Summary of findings:

- The perception of *sugar* and *white flour* as unhealthy increased in the intervention group after the intervention. Such changes were not seen in the control group
- The majority of women in both groups mentioned *vegetables* as part of a healthy diet both at baseline and post test. In the intervention group, fewer classified *meat* as part of a healthy diet at post test, compared to baseline. This was not observed in the control group.
- *Sugar* was mentioned by the majority as a factor that increases the risk of DM2. From baseline to post test, there was increased knowledge of some risk factors in the intervention group; *low physical activity*, *family with DM2*, *too much fat* and

overweight. In the control group, their knowledge of *low physical activity* had increased.

- The distribution of the participants in the intervention group with regard to stages of change had changed from baseline to post test. Many of the participants reported that they had now started to change dietary habits with regard to reduce and change type of fat, increase the intake of vegetables and legumes, and reduce intake of sugar and white flour. These changes were not observed in the control group.
- In the intervention group, the intake of soft drinks and fruit drinks with sugar added, and intake of whole fat milk and yoghurt were reduced from baseline to post test.
- Few reported a daily intake of foods high in fat and sugar, and no significant changes in intake of these foods were observed, except for an increase from baseline to post test of *sweet bakery goods* in the control group.
- The compiled intake of *fruits, fruit juice and vegetables* had increased in the intervention group. This was not seen in the control group. However, the total intake at post test was only 2.5 portions per day in the intervention group and 2 in the control group, i.e. only half or less of what is recommended.
- Intake of lean fish had increased in the intervention group, while there was an increase of fatty fish in the control group. The intake of fish was generally low, but the total intake of fish had increased in the control group. In the intervention group, this increase was not significant.
- The majority of women reported to use oil as a main source of fat in cooking. Women in both the control and intervention group reported to buy less oil per month at post test.
- The intake of white bread was reduced in the intervention group, while it had increased in the control group. There was not significant difference within or between the control and intervention group.

- The proportion of participants who reported a daily intake of cod liver oil had increased in the control and intervention group from baseline to post test, however, not significantly. There was a higher proportion in the control group than the intervention group who reported a daily intake at post test. The daily intake of vitamin supplements was also higher in the control group than the intervention group at post test.
- Changes in dietary intake of legumes and fruits were in agreement to the movement from the pre action to the action stages with regard to intentions to increase intakes of these foods.

This study has shown that in a group of women who generally have a low level of education, high level of illiteracy, and poor Norwegian language skills, culturally adapted health education increases their perceptions and knowledge of nutrition and health. Parallel to these findings, it was observed that the women in the intervention group reported that their intentions to change certain dietary habits had changed. The study also found agreement between the movement in stages of change and changes in dietary intake.

The process of acculturation has both positive and negative effects on dietary habits. Pakistani immigrants should be encouraged to preserve disease-protective traditional dietary habits. In this study, the perceptions and knowledge of vegetables as part of a healthy diet were high, and the intentions to increase intakes of vegetables as well as legumes had improved in the intervention group from baseline to post test. This study also showed that many considered food items, such as ghee, sugar and meat, unhealthy after the intervention. These are foods that are traditionally considered "strength foods". Prevention and management of DM2 and MS involves lifestyle changes, such as reduced intake of saturated fats, cholesterol, and trans fat in addition to increased intake of fibre, fruits and vegetables. Thus, the reduced purchasing of oil and reduced use of whole fat milk and yoghurt and drinks high in sugar, together with an increase in fruits and vegetables, are all important factors with regard to weight loss and prevention of the MS and DM2.

Based on the finding in this study, further research should also consider the use of focus groups in order to broaden the understanding of factors that affect these women's perceptions, food choice and dietary habits. Further research is also needed to measure the effect of education adjusted to the stage in which the participants are classified. This could maybe improve the outcome of culturally adapted health education.

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6. List of appendices